Prevalence and factors associated with Gestational Diabetes Mellitus among Antenatal women attending a Rural Health Centre in Vellore.

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Certificate

I hereby declare that this dissertation titled 'Prevalence and factors associated with Gestational Diabetes Mellitus among Antenatal women attending a Rural Health Centre in Vellore' is a bona fide record of my original research. It has not been submitted to any other university or institution for the award of any degree or Diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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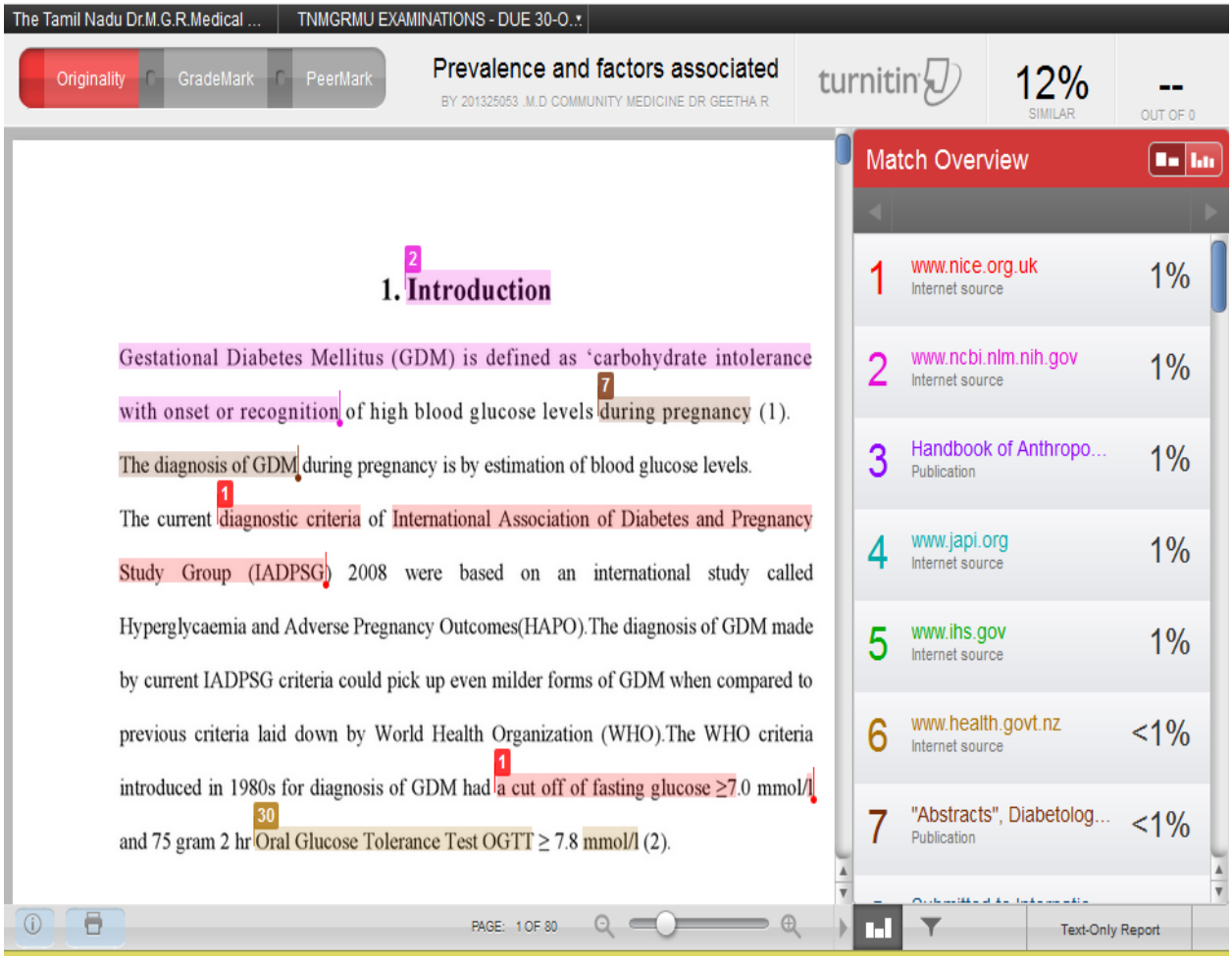

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Glossary of Abbreviations

GDM	Gestational Diabetes Mellitus
DM	Diabetes Mellitus
CHAD	Community Health and Development
IADPSG	International Association of Diabetes and Pregnancy Study Group
ACOG	American Congress of Obstetricians and Gynaecologists
HAPO	Hyperglycaemia and Adverse Pregnancy Outcomes
HBA1C	Glycated haemoglobin
FBG	Fasting blood glucose
OGTT	Oral Glucose Tolerance Test
GCT	Glucose Challenge Test
AGA	Appropriate for gestational age
LGA	Large for gestational age
PASE	Physical activity scale for elderly
PPAQ	Pregnancy physical activity questionnaire
OPD	Outpatient department
BMI	Body Mass Index
SFT	Skin Fold thickness
MET	Metabolic equivalents on testing
HCS	Human Chorionic Somatotropin
GOD-POD	Glucose Oxidase - Peroxidase method
NIN	National Institute of Nutrition
WHO	World Health Organization

Tables

Figures

Table of Contents

For Dissertation submitted to Tamilnadu Dr.M.G.R Medical University

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ABSTRACT

Title: Prevalence and factors associated with Gestational Diabetes Mellitus among antenatal women attending a rural health center in Vellore

Background: Gestational Diabetes Mellitus is one of the significant causes of maternal and fetal morbidity. The prevalence of GDM is low in western world and high in South East Asia. The prevalence in India varies according to the criteria used and the population studied.

Objective: 1) To estimate the prevalence of Gestational Diabetes Mellitus (GDM) among antenatal women attending a Rural health Centre attached to Christian Medical College, Vellore.2) To study the associations between anthropometry, parental history, physical activity of pregnant women and GDM. 3) To compare the dietary energy intake of antenatal women with and without Gestational Diabetes Mellitus.

Methods: A hospital based cross sectional study among pregnant women. 630 women recruited for OGTT. GDM diagnosed as per IADPSG criteria at 24 to 28 weeks. Among 563 who underwent OGTT all 75 GDM women and subset of women without GDM selected randomly and were visited at their homes. The study tool used was semi structured questionnaire; PPAQ (pregnancy physical activity questionnaire), 24 hrs dietary recall, and skin fold thickness measurements.

Results and conclusions: The hospital based prevalence of GDM was 14% (95 % CI: 11.3% to 16.7%). Women with family history of DM had 2.65 times risk of GDM adjusted OR 2.65(1.34 to 5.25) , women with body fat of more than 23% 2.89 times risk

of GDM adjusted OR 2.89(1.47 to 5.68). The age specific prevalence showed an increasing trend.chi square of trends=15.186($p<0.001$)

It was concluded from the study that universal screening of GDM is needed. In primary and secondary care settings where universal screening is not done selective screening to include early pregnancy BMI and body fat percentage.

1. Introduction

Gestational Diabetes Mellitus (GDM) is defined as 'carbohydrate intolerance with onset or recognition of high blood glucose levels during pregnancy (1).

The diagnosis of GDM during pregnancy is by estimation of blood glucose levels.

The current diagnostic criteria of International Association of Diabetes and Pregnancy Study Group (IADPSG) 2008 were based on an international study called Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO). The diagnosis of GDM made by current IADPSG criteria could pick up even milder forms of GDM when compared to previous criteria laid down by World Health Organization (WHO).The WHO criteria introduced in 1980s for diagnosis of GDM had a cut off of fasting glucose ≥7.0 mmol/l and 75 gram 2 hr Oral Glucose Tolerance Test OGTT ≥ 7.8 mmol/l (2).

The prevalence of GDM is less in western countries when compared with Mediterranean and South East Asian countries. The prevalence of GDM in Canadian population is 2.5% (3). Studies from the Middle East like Saudi Arabia have documented the prevalence of GDM to be 12.5%(4).The prevalence of GDM in India varies between regions. From a study done at Haryana, the hospital based prevalence of GDM was 7.1%(5).The prevalence in a hospital at Lucknow, Uttar Pradesh was 41.9%(6).The prevalence of GDM in Tamilnadu from a community based study done at Chennai was 17.8%in urban,13.8%in semi urban and 9.9% in rural areas of Tamilnadu (7). In a study in southern part

of Tamilnadu at Trichirapalli, the prevalence of GDM in a tertiary hospital was 23% (8).

The consequences of GDM affect both the mother and foetus. Gestational diabetes Mellitus is one among various causes during pregnancy that can lead to poor outcomes of pregnancy which include macrosomia, pre term birth, still birth, shoulder dystocia, congenital malformations, hypoglycaemia of the new born and unexplained foetal deaths. Maternal outcomes include poor glycemic control during pregnancy, susceptibility to infections, cephalo-pelvic disproportion, operative deliveries, type II diabetes in later life (3, 9, 10)

Studies show that GDM if treated resulted in significant decline in the relative risks of occurrence of Macrosomia (RR = 0.47), large for gestational age (RR = 0.57), shoulder dystocia (RR = 0.41).Also the risk of perinatal mortality, admissions to neonatal intensive care units (NICU), trauma at birth was reduced (11). Proper and expected management would result in decrease of poor perinatal, maternal and neonatal outcomes, decrease admission of newborns to ICUs and decrease hospital stay (12).

2. Justification

Before the findings of the HAPO study became available, selective screening was in practice to detect GDM among pregnant women. However, after the HAPO study results there was a paradigm shift in the approach to diagnose GDM, as the HAPO study showed that high glycemic levels lower than the then existing standard cut off levels prescribed by WHO led to significant complications in the perinatal period. Based on the HAPO study, the IADPSG guidelines recommends universal screening of pregnant women for GDM. The screening is a two-step process. The first step is estimation of fasting blood glucose levels in early pregnancy, followed by 75 gram 2 hr OGTT at 24 to 28 weeks for women who test normal in the initial screening.

The Indian guidelines issued by government approved Diabetes In Pregnancy Study Group India (DIPSI)for screening and diagnosis of GDM recommends 2 hr blood glucose estimation by Glucose Oxidase-Peroxidase method (GOD - POD) after administration of 75 grams of glucose(13). The cut of ≥140 mg/dl is considered as both screening and diagnosis of GDM. The advantages are that pregnant woman need not be in a fasting state at the time of the test and the possibility of drop out from antenatal visit is less.

The State Health System in Tamilnadu practices universal screening of pregnant women at 12 to 16 weeks, 24 to 28 weeks, and 32 to 34 weeks by doing 75 grams 2 hrs OGTT (14). In Primary Health Centres where lab technicians are not available nurses are trained to do the test using a semi auto analyser. But although guidelines exist, if the equipment is not functioning at the centre fasting and random blood glucose by Glucometer is done to check

glucose levels (14). The private health care sector in Tamilnadu follows the screening procedures according to the treating doctor's preference of the investigation. Most commonly 75 grams OGTT at 24 to 28 weeks is done as most private Obstetricians follow Federation of Obstetrics and Gynaecology Society of India guidelines (FOGSI).

The Obstetrics and Gynaecology department of Christian Medical College, Vellore follows the IADPSG guidelines of universal screening of pregnant women by a two-step process. The detailed method of screening is given in the forth coming sections.

The Rural Health Centre attached to Christian medical college, Vellore is run by the Department of Community Health through its 110 bed Community health and Development (CHAD) Hospital. The hospital had been doing high risk screening among antenatal women to detect GDM.OGTT was performed only on women who had significant family history of diabetes, previous bad obstetric history or high risk pregnancy. The people attending CHAD hospital are from Kaniyambadi block and also from neighbouring towns of Polur, Arni and Ranipet. Hence a hospital based study to estimate the prevalence and determinants of GDM among the ante natal women attending the Rural Health Centre would help in reducing the maternal morbidity, perinatal mortality and morbidity among antenatal women seeking health care in CHAD hospital. This

would also help with prevention and management of GDM during pregnancy, childbirth and in later life.

3. Objectives

1) To estimate the prevalence of Gestational Diabetes Mellitus (GDM) among antenatal women attending a Rural Health Centre attached to Christian Medical College, Vellore.

2) To study associations between

a) Nutritional anthropometry of pregnant women and Gestational Diabetes Mellitus.

b) Parental diabetic status and Gestational Diabetes Mellitus.

c) Physical activity patterns and Gestational Diabetes Mellitus.

3) To compare the dietary energy intake of antenatal women with and without Gestational Diabetes Mellitus.

4. Literature review

4.1 Definition of Gestational Diabetes Mellitus:

Gestational diabetes is defined as 'carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy' (1).There lays a possibility that unrecognized intolerance to glucose present before pregnancy would also be diagnosed as GDM. This definition is accepted standard definition used in the medical world (1).

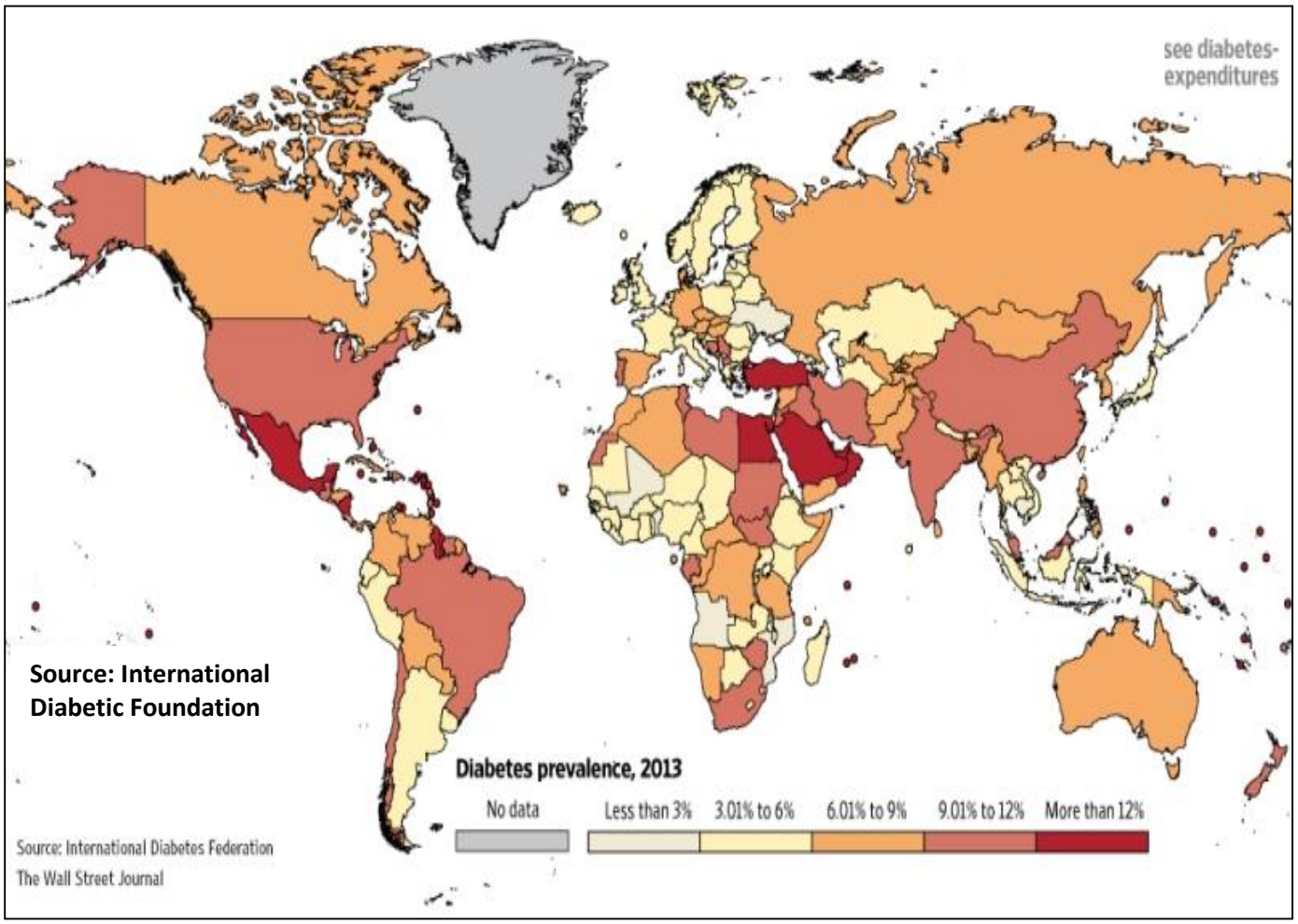
4.2 Prevalence of Type II Diabetes Mellitus:

The WHO has documented the global prevalence of Diabetes Mellitus (DM) Type II of the year 2012 among adults 18 years of age and above to be 9%(15).More than 80% of Diabetic deaths occur in low and middle income countries(15). The following Figure4.1 illustrates the prevalence of Diabetes mellitus for the year 2013.India has a prevalence of Type II Diabetes Mellitus above 18 years of age from 9% to 12%. The number of people with Diabetes Mellitus above 18 yrs of age in the year 2000 was 31,705,000 and the estimate for the year 2030 is 79,441,000(15).

4.3 Prevalence of GDM:

The prevalence of GDM varies between countries and between ethnic groups. The prevalence of GDM is 2.5% in Canadian population (3). Studies from Middle East like Saudi Arabia showed prevalence of GDM to be of 12.5% (4). The hospital based prevalence of GDM in India varies between regions. The prevalence of DM Type II in various countries is shown by Figure: 4.1. From a study done at Haryana the hospital based prevalence of GDM was 7.1% (5) .The prevalence in a hospital at Lucknow, Uttar Pradesh was 41.9% (6).In a study in southern part of Tamilnadu at Trichirapalli, the hospital prevalence of GDM was 23%(8).The community based prevalence of GDM in Tamilnadu study done at Chennai was 17.8%in urban, 13.8%in semi urban and 9.9% in rural areas of Tamilnadu (7).

Figure: 4.1: Prevalence of Diabetes Mellitus Type II in the world 2013



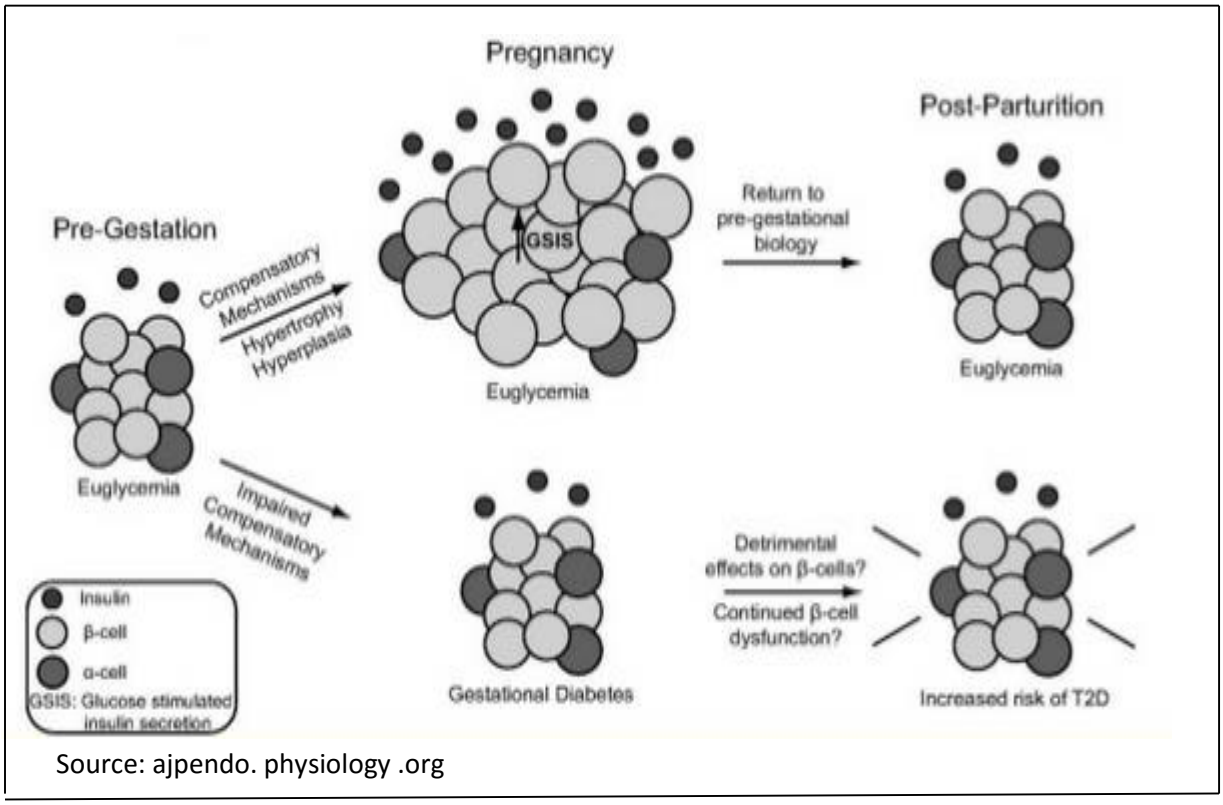
4.4 Diabetes Mellitus before pregnancy:

Women known to have Diabetes Mellitus before onset of pregnancy are termed as 'Diabetes Mellitus and pregnancy' and not as GDM (1). The presence of Diabetes before pregnancy could be Type I Diabetes Mellitus. Those with Type I Diabetes would have high

glucose levels and it has to be detected in early pregnancy. The various methods of screening available are discussed in forth coming sections.

4.5 Pathophysiology of GDM:

Figure 4.2 Pathophysiology of GDM and insulin resistance



Source: ajpendo. physiology .org

Earlier studies done on pathophysiology of Gestational Diabetes have demonstrated the presence of islet cell antibodies in patients diagnosed with GDM in the range from 10% to 35%(16) and suggested type I nature of the disease. But later studies showed that specific monoclonal antibodies against beta cells of pancreas among GDM patients are very less in the range of 1 to 2%(17) and demonstrated the type II nature of the disease thereby proving

that GDM was not due to antibody mediated (Type I) diabetes. Studies done among postpartum women who had GDM have also demonstrated defects in insulin sensitivity and insulin secretory response which suggested (Type II) nature of the disease (17). Thus among the women who have a genetic predisposition the metabolic stress of pregnancy would lead to GDM.

4.6 Diagnosis of GDM over the years:

Initially hyperglycaemia was detected in pregnancy and its adverse pregnancy outcomes was published in 1960s and the diagnostic criteria of 3 hr 100 grams glucose test was validated and accepted (18-20).

Table: 4.1: Most commonly used guidelines for Diagnosis of GDM

Organization	Fasting Plasma Glucose	Glucose Challenge	1 hrs. plasma glucose	2 hrs. plasma glucose	3 hrs. plasma glucose
WHO 1999*	≥ 7.0 mmol/l	75 g OGTT	Not required	≥ 7.8 mmol/l	Not required
ACOG**	≥ 5.3 mmol/l	100g OGTT	≥ 10.0 mmol/l	≥ 8.6 mmol/l	≥ 7.8
Canadian Diabetes Association***	≥5.3 mmol/l	75 g OGTT	≥ 10.6 mmol/l	≥ 8.9 mmol/l	Not required
IADPSG******	≥ 5.1 mmol/l	75 g OGTT	≥ 10.0 mmol/l	≥ 8.5 mmol/l	Not required

*One value is sufficient for diagnosis
**Two or more values are required for diagnosis
***Two or more values required for diagnosis
**** One value is sufficient for diagnosis

Source :WHO/repository for information sharing /NMH/13.2

Over the period of years, 75 gram oral glucose tolerance test became the standard of practice to diagnose Diabetes Mellitus Type II. WHO adopted this criterion to diagnose GDM since 1999. The various guidelines used to diagnose GDM over the period of years are provided in Table 4.1 In 2008 before the publication of HAPO study results Canadian Diabetic Association recommended 2 hr-75 grams glucose to screen women in pregnancy for GDM (18). In 2011, the ACOG recommended a two-step process of GDM diagnosis. The first screening with 50 grams of glucose 1hr challenge test at 24 to 28 weeks and the women found to have abnormal glycemic levels to undergo the confirmatory 3 hr - 100 grams OGTT at 24 to 28 weeks (19).

4.7 The Hyperglycaemia and adverse pregnancy outcomes (HAPO) study:

The HAPO multi-centric study was conducted across 10 countries and included 25,505 pregnant women from 15 centres. The participants were administered 75-g oral glucose-tolerance test between 24 to 32 weeks of gestation. The primary outcomes studied were birth weight above the 90th percentile for gestational age, primary caesarean delivery, clinically diagnosed neonatal hypoglycaemia, and cord-blood serum C-peptide level above the 90th percentile. Secondary outcomes studied included pre term delivery, shoulder dystocia, birth injury, need for intensive neonatal care, elevated billirubin levels and pre-eclampsia (21).

The HAPO study results published in 2008 showed that there was a positive and continuous association of maternal glucose levels below that diagnostic criterion of GDM, which were

in practice until that time. It also proved positive association between diabetes and increased birth weight and increased cord-blood serum C-peptide levels.

For an increase in FBG (fasting blood glucose), 1 hr BG (blood glucose), 2 hr BG by one standard deviation the adjusted odds ratio for primary outcomes were calculated. It was found that for birth weight above 90th percentile the odds ratios were 1.38(95% CI: 1.32 to 1.44), 1.46 (1.39 to 1.53), and 1.38 (1.32 to 1.44) respectively. The C peptide levels above 90th percentile had an odds ratio of 1.55 (95% CI: 1.47 to 1.64), 1.46 (95% CI: 1.38 to 1.54), and 1.37 (95% CI: 1.30 to 1.44) respectively. The odds ratios for caesarean delivery were 1.11 (95% CI, 1.06 to 1.15), 1.10 (1.06 to 1.15), and 1.08 (1.03 to 1.12); and for neonatal hypoglycaemia, 1.08 (95% CI, 0.98 to 1.19), 1.13 (1.03 to 1.26), and 1.10 (1.00 to 1.12) respectively (21). Significant associations observed for secondary outcomes were weaker. This study conclusively identified strong associations between maternal glucose levels and several perinatal outcomes.

4.8 Diagnosis of GDM- current IADPSG criterion:

Gestational Diabetes Mellitus is diagnosed by the International Association of Diabetic and Pregnancy Study Group (IADPSG) 2008 recommendations (22).

The recommendations were drawn on the findings of the Hyperglycaemia and Adverse Pregnancy Outcomes-HAPO study (21) which is a multinational, multicultural ethnically diverse study which is elaborately described above.

The guide line is to diagnose GDM according to Glycated haemoglobin (HbA1C) ≥6.5% or Fasting Blood Glucose (FBG) ≥5.9 mmol/dl or ≥92 mg/dl at first prenatal visit. If the FBG value is <92 mg/dl, then GTT is to be done at 24 to 28 weeks of gestation to find whether the mother has turned to be having GDM later in pregnancy. The cut off values for diagnosis of GDM are ≥ 92/180/153 mg /dl or 5.1/10/8.5 mmol/dl in fasting, 1hour and 2 hours venous samples after oral administration of 75 grams of glucose respectively (22).The recommended kits for OGTT are DCCT/UKPDS (DCCT-Diabetes control and complication trial assay, UKPDS-United kingdom Diabetes Study Assay).The following Figure 4.2 illustrates the diagnostic cut off used in IADPSG criteria.

Figure: 4.3: IADPSG criteria for diagnosis of Gestational Diabetes Mellitus

Diagnosis of hyperglycemia in pregnancy

Table 1—*Threshold values for diagnosis of GDM or overt diabetes in pregnancy*

To diagnose GDM and cumulative proportion of HAPO cohort equaling or exceeding those thresholds

	Glucose concentration threshold*		Above threshold (%)
Glucose measure	mmol/l	mg/dl	Cumulative
FPG	5.1	92	8.3
1-h plasma glucose	10.0	180	14.0
2-h plasma glucose	8.5	153	16.1†

To diagnose overt diabetes in pregnancy

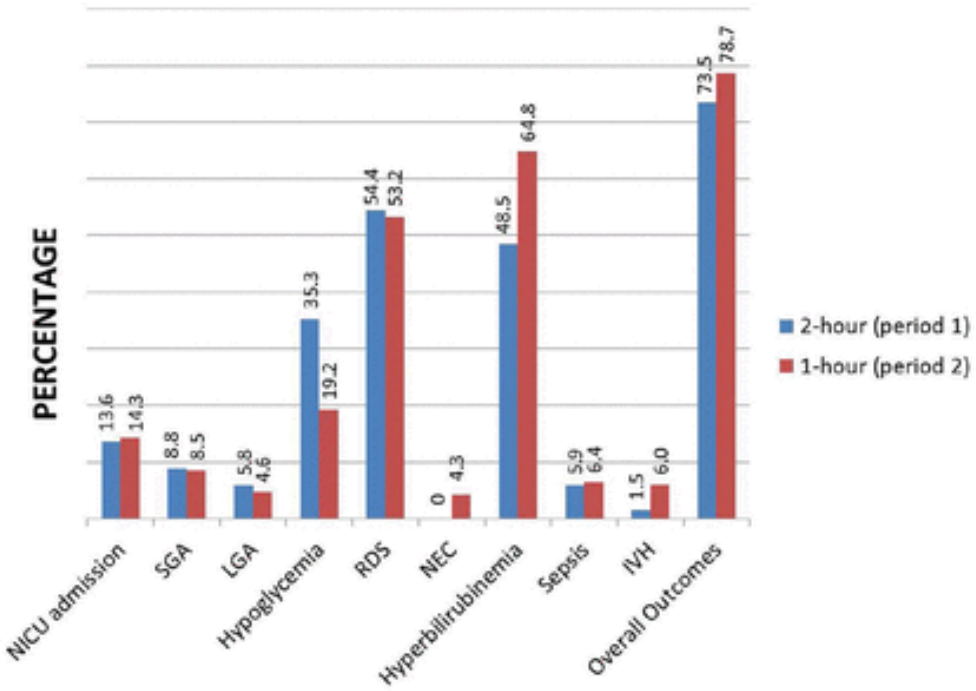
Measure of glycemia	Consensus threshold
FPG‡	≥7.0 mmol/l (126 mg/dl)
A1C‡	≥6.5% (DCCT/UKPDS standardized)
Random plasma glucose	≥11.1 mmol/l (200 mg/dl) + confirmation§

Source: American diabetic association/ Diabetes care journal/ March 2010

4.9 One step Vs two-step process of screening for GDM:

One among various studies done to find the best approach to screen GDM after the HAPO study is a cohort study done in Women's Ambulatory health services clinic at Hartford. This study screened 812 pregnant women at 24 to 28 weeks of pregnancy or GDM. The women who were screened with two steps (ACOG guidelines) process 7% were diagnosed to have GDM. Out of the women who underwent one step process of diagnosis of GDM 11.7% were diagnosed to have GDM (23). The new IADPSG criteria based on HAPO picks up women with impaired glucose tolerance as evidenced by many studies. After follow up on neonatal outcomes this study concluded that there was no significant difference between both methods of screening on neonatal outcomes ($p>0.05$)

Figure: 4.4 Study results of one step screening Vs two step screening on neonatal outcomes



Source: clinical diabetes journal Oct 2014

4.10 Cost utility analyses of various methods of screening for GDM:

There were relatively fewer studies for cost analyses of screening for GDM. One cost utility analyses done at United States of America (U.S.A) which took three methods of GDM screening.

One is the two step 50 g glucose followed by 100 grams OGTT, second is the 75 g glucose one step screening, third is the 100 grams OGTT method. The previous studies published on GDM screening were used to generate the effectiveness model. Sensitivity and Specificity of the screening tests, Quality Adjusted Life Years (QALY) was considered as outcome measures. The 75 g OGTT had sensitivity of 80% and specificity of 86%. The 100 g OGTT had sensitivity and specificity of 100%.

After analysing direct costs, indirect costs the cost utility was analysed for 4% prevalence of GDM. The expected costs were $2836 for two step screening, $2874 for 100 g glucose, $ 2895 for 75 g OGTT and $ 2995 for no screening in the maternal model. The expected costs were $ 77 for two step screening, $ 89 for 100 g glucose OGTT, $ 91 for 75 g OGTT and $ 80 for no screening (24).

The conclusion arrived was that two step screening was cost effective in U.S.A. It was also concluded that 100 g OGTT could be used to screen GDM in more prevalent populations like Hispanics. Although the cost utility analyses showed that two step method of screening was better the generalisability of the results was not mentioned in the study.

4.11 GDM and foetal outcomes:

4.11.1 GDM and short term foetal outcomes:

GDM can lead to Macrosomia, still births, pre-term births, early neonatal deaths in the foetus (25, 26). Macrosomia refers to large babies with birth weight of more than 4 kilograms. Studies have proved that the presence of high glycemic environment in uterus is responsible for Large for gestational age (27). Macrosomia causes problems during perinatal period and leads to difficult modes of delivery of the baby like caesarean section, forceps delivery (26, 27) which lead to external trauma. Babies born to mothers with GDM are prone to have hypoglycaemia in their early neonatal period.

4.11.2 Pathophysiology of Macrosomia:

Macrosomia means large babies weighing more than 4 kg at birth. Women with GDM have increased peripheral resistance to insulin and decreased sensitivity which is the more common pathophysiology apart from antibody mediated GDM. The Human chorionic somatotropin (HCS) is partly related to secretion of insulin in foetus and inhibition of peripheral uptake of glucose in the mother (28).Because of the raised glycemic levels in the maternal blood foetal pancreas gets stimulated and starts to secrete insulin after 11th or 12th week of gestation. Since insulin is an anabolic hormone elevated insulin levels leads to large growth of the baby and macrosomia (29-31).

4.11.3 GDM and short term foetal outcomes – congenital anomalies:

In a cohort study done for 15 years at the National Women's Hospital, Auckland, 221 women with Type I diabetes, 315 women with Type II diabetes prior to pregnancy and 1822 women with gestational diabetes were followed up during pregnancy and also during their postpartum period. Out of the 1822 GDM women 13% had a positive OGTT after delivery. This study had mixed population of Europeans and people of Asian origin.

All the pregnant underwent ultrasound at 16 to 20 weeks of gestation and newborns were examined after delivery for congenital anomalies (32).

In Type I diabetes women the incidence of major congenital anomalies was 5.9%, in Type II diabetes the incidence was 4.4% and 1.4% in women with GDM. The incidence of major congenital anomalies was 4.6% in newly recognized diabetes group which was similar to incidence seen in Type I diabetes and Type II diabetes group. The other women in the GDM group had incidence of major congenital anomalies lower than all the other groups with p value <0.001(32). From this study it could be concluded that newborns of Type I and Type II diabetic mothers have higher risk of major congenital anomalies. The newborns of GDM mothers carry a lower risk than Type I and Type II but higher risk than general population in the incidence of major congenital anomalies.

4.11.4 GDM and long term foetal outcomes: metabolic syndrome

A cohort study was done at Rhode Island Hospital by following up children of mothers with GDM and mothers without GDM and children born large for gestational age (LGA) and appropriate for gestational age (AGA). The primary marker of metabolic syndrome like obesity, dyslipidemia, glucose intolerance and hypertension were considered as outcomes and were elicited at 6, 7, 9, 11 years. Presence of any two or more than two of the outcomes was considered as criteria for metabolic syndrome. It was found in the study that the prevalence of metabolic syndrome was 15% among children who were large for gestational age and had gestational diabetic mothers (LGA / GDM) (33). The other groups were AGA/GDM, LGA/control, and AGA/control. These groups had a prevalence of metabolic syndrome of 4.8% which was similar to the prevalence in general population. It was also found that exposure of foetus to maternal obesity was a strong predictor of risk of metabolic syndrome and LGA status (33).

4.11.5 GDM and long term foetal outcomes: intelligence levels of offspring:

A cohort study followed up the children of GDM mothers and intelligence of the children assessed through Bayley scale of infant development (BSID) and Stanford Binet intelligence scale. The Bayley scale was administered at the age of two and Stanford Binet scale at age of three, four and five. It was found from the study that the intelligence levels were inversely proportional to Beta hydroxy butrate levels and free fatty acid levels in third

trimester of pregnancy after correcting for women with pre gestational diabetes, gestational diabetes and no diabetes (34).

Beta hydroxyl butrate is an organic compound generated from liver during fasting state. It is not a ketone but the levels increase during ketosis. Thus regardless of the type of diabetes what the women had, ketosis due to uncontrolled sugar or prolonged fasting stage could lead to decreased intelligence levels in the children born to women with high glycemic levels.

4.12 GDM and Maternal outcomes

4.12.1 GDM and short term maternal outcomes:

GDM in pregnancy leads to maternal complications particularly more during the perinatal period. The poor outcomes are abnormal mode of deliveries (21). A retrospective cohort study done for seven years showed that mothers with GDM were at significantly increased risk of gestational hypertension adjusted OR: 1.26 (95% CI: 1.21–1.32), pre-eclampsia adjusted OR: 1.30 (95%CI: 1.20–1.41), premature rupture of membranes adjusted OR: 1.13 (1.06–1.20), caesarean section adjusted OR: 1.13 (1.10–1.17), and preterm delivery adjusted OR: 1.13 (1.08–1.18) (3).

4.12.2 GDM and Hypertension during pregnancy

Hypertension during pregnancy also called as Gestational Hypertension was significantly associated with GDM in previous studies. A Japanese study was done on 2651 consecutive

pregnant women and GDM and hypertension was screened at 24 to 27 weeks of pregnancy. The GDM was screened using the two step method of 50 g glucose challenge followed by 75 g 2 hr OGTT. It was found from the study that gestational hypertension among impaired glucose tolerant women was 5.8% and among GDM women was 8.2% and both were significantly greater than women without GDM (p value <0.01) (35). However the incidence of Gestational hypertension was 2.2% among impaired glucose tolerant women and 4.1% among GDM women and was not significantly different from women with normal glycemic levels.

Another population study done in Australia showed that GDM was associated with hypertension during pregnancy after adjusting for all confounding factors with risk of OR 1.69 (95 % CI : 1.4 to 1.9)(36).

The relationship between hypertension/ pre-eclampsia and GDM was explored in an animal study which proved that placental growth factor was reduced in pre-eclampsia and was the cause of reduced proliferation of pancreatic beta cells which thereby led to GDM. Mice were injected with chemical substances which mimicked hypertension and pancreatic beta cell function was studied. There was a significant association between hypertension induced mice and reduced placental growth factor levels and. There was a reduced growth of beta cells of pancreas in mice which had reduced placental growth factor levels suggesting the association between hypertension and impaired beta cell function (37).

Scientific studies have also proven than a reduced potassium level in early pregnancy was a protective factor against occurrence of GDM and preeclampsia. The potassium levels of

women in early pregnancy was checked and they were classified in to groups with potassium levels < 3.5 meq/l, 3.5 to 3.99 meq/l, 4 to 4.99 meq/l and >5 meq/l. It was found that the rates of pre-eclampsia were 0.4%, 0.9%, 1.3% and 1.5% among the groups respectively which showed the protective nature of the low potassium levels. Among the group which ha d potassium levels more than 5 meq/l the occurrence of both GDM and pre-eclampsia was significantly associate ($p = 0.027$) (38).

4.12.3 GDM and Pre-eclampsia – Association with oxidative stress:

The recent scientific studies had proven that markers of oxidative stress include prostaglandins and more specifically epimers of prostaglandins like 8 iso PGF2α are significant predictors of GDM and also hypertension during pregnancy.

A study was done on women recruited to HAPO study to find the association between 8 iso PGF2α and risk of developing GDM and hypertension. The blood samples were taken at fasting at the time of OGTT at 24 to 32 weeks and also once at 34 to 37 weeks.

Significant correlations were observed between maternal fasting plasma 8 iso PGF2α and both fasting $r = 0.20$ (p value < 0.001) and 2-hour $r=0.39$ (p value < 0.001) plasma glucose levels at the time of OGTT. Gestational hypertension/pre-eclampsia occurred in 17 (4.2%) women, and at the time of OGTT, they had significantly higher fasting plasma 8-isoPGF$_{2\alpha}$ (p value < 0.001), urine 8-isoPGF$_{2\alpha}$ (p value < 0.005) and urine 2,3-dinor 8-isoPGF$_{2\alpha}$ to creatinine ratios (p value < 0.001), as well as higher MAP (p value < 0.001) than women who remained normotensive. At 34–37 weeks, only random plasma 8-isoPGF$_{2\alpha}$ was

significantly higher (p value < 0.001) among the women with gestational hypertension/pre-eclampsia (39). The study concluded that oxidative stress in early pregnancy was significantly associated with development of GDM and hypertension during pregnancy.

4.12.4 GDM and long term maternal outcomes:

The postnatal complications for the mother who had GDM are minimal but long term complications like the risk of developing Diabetes Type II is high. The risk of developing diabetes was 6.9% at five years and 21.1% at ten years following the initial diagnosis of GDM (9, 10). Standard care of GDM management is to test the postnatal mother at 6weeks with OGTT to know whether the sugars have come down to normal levels. Because of the development of Diabetes Type II in future there is a marginal risk of developing CVD-Cardio vascular diseases in future (9).

In a Meta-analysis done out of 28 studies which had follow up of GDM patients it was found that the cumulative incidence of Diabetes was 2.6% at 6 weeks post-partum to 70% in 28 yrs follow up(10). The cumulative incidence increased in the first five years after confinement in mixed study populations or those without white women. It was found in the Meta analysis that elevated fasting glucose was a risk factor associated with type II Diabetes in future. The explanation given by the authors is that the women with elevated fasting glucose carry with them the same level of insulin resistance and later develop type

II Diabetes. In one cohort study 1822 GDM women were followed up and 13 % of them had high glycemic levels six weeks after delivery and they were termed as 'newly diagnosed Diabetes' (32).

4.13 Risk factors of GDM:

4.13.1. Maternal obesity:

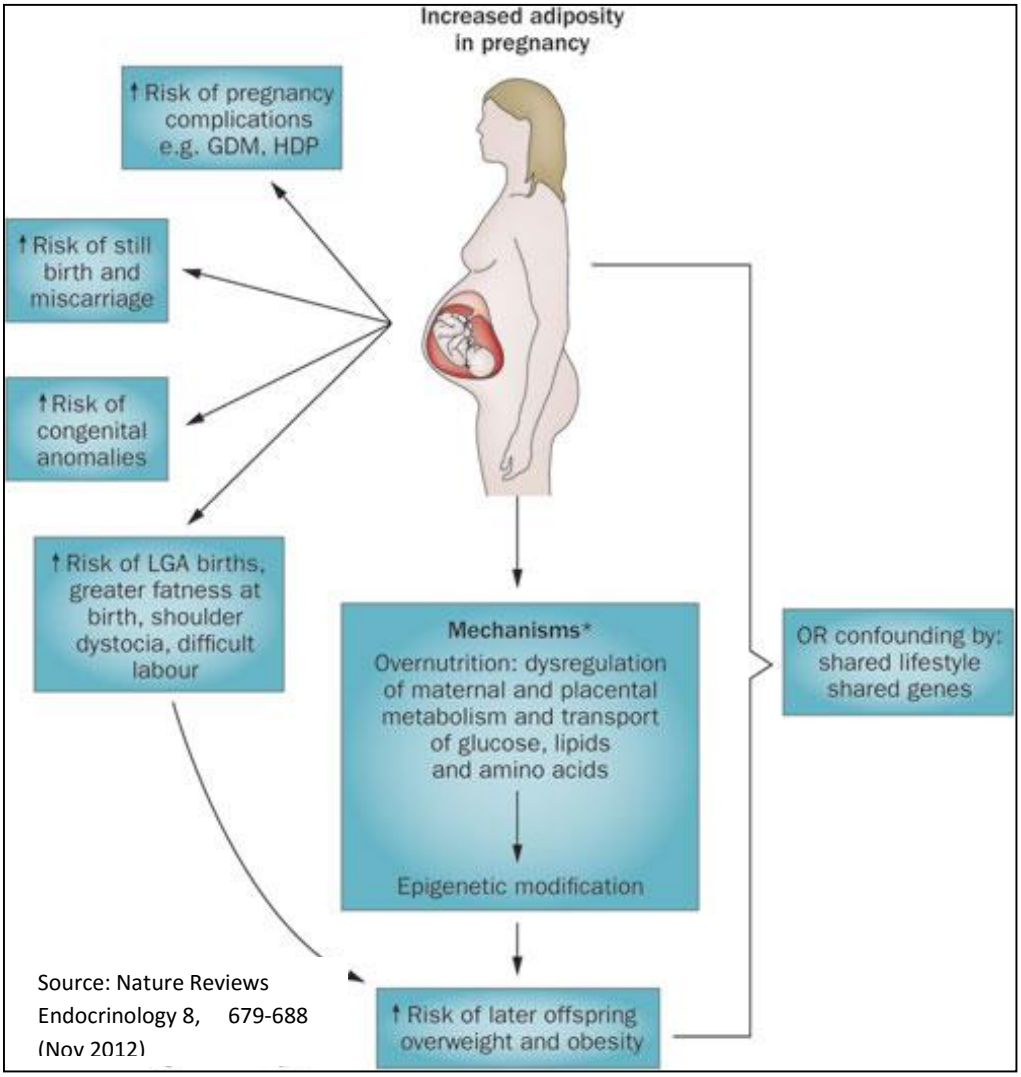
A retrospective study showed that compared to normal weight, overweight women and obese women have greater risks of gestational diabetes mellitus with adjusted OR=2.13 (95% CI: 1.52 to 2.98) and adjusted OR=2.85 (95% CI: 2.01 to 4.04) respectively. The adjusted odds for getting gestational hypertension was OR=2.01 (95% CI: 1.27 to 3.19) and OR=4.79 (95% CI: 3.13 to 7.32) and preeclampsia OR=3.16 (95% CI: 1.12 to 8.91) and OR=8.80 (95% CI: 3.46 to 22.40) respectively. The risk of oligo hydramnios in obese women is adjusted OR=2.02 (95% CI: 1.25 to 3.27), polyhydramnios is OR=1.76 (95% CI: 1.03 to 2.99), vaginal tears is OR=1.24 (95% CI: 1.05 to 1.46). There was a lower risk of induced deliveries among obese women OR=0.83 (95% CI: 0.72 to 0.95) (40). A Meta-analysis done on 20 cohort studies published from 2001 to 2006 showed that the pre pregnancy BMI and risk of developing GDM are significantly associated. The unadjusted ORs of developing GDM were 2.14 (95% CI 1.82 to 2.53), 3.56 (3.05 to 4.21), and 8.56 (5.07-16.04) among overweight, obese, and severely obese women compared with normal-weight pregnant women, respectively (41).

4.13.1.2 Relationship between body fat and GDM:

In a cohort study done on multi ethnic population at Oslo University, the association between weight gain, fat in trunk of the body, skin fold thickness and GDM were explored. The study took IADPSG criteria for diagnoses of GDM. The number screened was 728 and height, weight gain, fat and skin fold thickness was measured for all the pregnant women screened. The measurements were done at 15 weeks and 28 weeks. The objective was to find whether increase in the indicators of obesity like fat mass, skin fold thickness was associated with GDM. It was found that weekly increase in truncal body fat of 0.14 kg was associated with occurrence of GDM with adjusted OR of 1.31 (95% CI: 1.10 to 1.56).increased weight gain was associated with GDM with adjusted OR 1.23 (95% CI: 1.04 to 1.46)(42). It was also found that the skin fold thicknesses of South Asian and east Asian population was more when compared with Europeans, Middle East and African population.

In this study after adjustment for pre pregnancy BMI, truncal fat it was found that south Asians have 5.9 times risk of having GDM (95% CI: 3.5 to 10.0) than Europeans who have 2.1 times risk of having GDM (95% CI: 1.6 to 2.8)(42). It was concluded from the study to discourage South Asians from excess weight gain during pregnancy.

Figure: 4.5 Impact of excess body fat on pregnancy outcomes



4.13.1.3 Measurement of obesity by body fat estimation in pregnancy:

Studies have standardized the skin fold thickness measurement of biceps, triceps, sub scapular and mid arm circumference for calculating the body fat percentage and can be reliably used in research (43) for estimating BMI. The standard methods of body fat

measurement methods like Dual energy X-ray absorptiometry, Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) cause radiation to foetus and are not advised during pregnancy. The body fat can be calculated from various skin fold thicknesses by the following formula (43) given in Figure 4.4.

Figure: 4.6: Formula for calculating Body Fat Percentage from Skin fold thickness

Body fat% = 12.7 + (0.457 x triceps SFT) + (0.352 x subscapular SFT) + 0.103 x (Biceps SFT – 0.057) x height + (0.265 x MUAC)

SFT – Skin fold thickness
MUAC – Mid upper arm circumference

Source: BMC Pregnancy and Childbirth 2013; kannieappan et al (personal communication, Timothy Olds, 15/09/12)

The percentage of essential body fat for women is greater than that for men, as a resource for demands of child bearing and other hormonal functions. Body fat percentage of more than 30% for men and more than 25% for women is considered as obesity (44).The other standard measure of obesity measurement is by BMI estimation using Body Mass Index. It is calculated by weight in kilograms/ (height in meter^2). The WHO had prescribed standard BMI cut offs to classify underweight, over weight and obesity. The WHO standard criterion to diagnose obesity is a BMI equal to or above 30 as shown in shown in Table 4.2 (45).

Table: 4.2: International Classification of Underweight, Overweight, Obesity according to Body Mass Index

Classification	Principal cut off points
Under weight	< 18.50
Severe thinness	<16.00
Moderate thinness	16.00 – 16.99
Mild thinness	17.00 – 18.49
Normal range	18.50 – 24.99
Overweight	≥ 25.00
Pre obese	25.00 – 29.99
Obese	≥ 30.00
Obese class I	30.00 – 34.99
Obese class II	35.00 – 39.99
Obese class III	≥ 40
Source: WHO: Technical report series: 894/ 1995 Adapted from 1995/2000/2004	

4.13.2 Low levels of physical activity

The studies of the effect of physical activity on GDM show it to be a significant protective factor. A study done in 1997 which measured physical activity during pregnancy in mean metabolic equivalent expenditures found that there was no significant risk reduction in GDM by doing vigorous activity or walking (46). A cohort study was done from subjects of project viva at Massachusetts with 1805 women. The Television viewing and physical

activity time of the women was assessed before and after pregnancy. Among them 17% of women developed GDM and 83% of women had normal glucose tolerance. After adjustment for age, race or ethnicity, history of GDM, family history of diabetes, and pre pregnancy body mass index, it was found that the women who did vigorous physical activity in the year before pregnancy experienced a reduced risk of GDM OR 0.56 (95% CI: 0.33 to 0.95) and abnormal glucose tolerance OR 0.76 (95% CI 0.57 to 1.00) (47).Women who reported vigorous activity before pregnancy and light-to-moderate or vigorous activity during pregnancy appeared to have a lower risk of both GDM OR 0.49 (95% CI 0.24 to 1.01) and abnormal glucose tolerance OR 0.70 (95% CI 0.49 to 1.01) compared with women reporting these activities in neither time period(47). Walking and total physical activity provided modest benefits. There was no association between television viewing before or during pregnancy with risk of GDM or abnormal glucose tolerance. This particular study was a cohort study and physical activity were measured before pregnancy and after pregnancy using the questionnaire PASE (Physical Activity Scale for Elderly) and all the recruited women were tested for GDM during pregnancy. This study showed that physical activity before and during pregnancy was a protective factor against GDM and abnormal glucose tolerance.

A Meta-analysis on physical activity and GDM showed that pre pregnancy physical activity, physical activity during pregnancy had the pooled odds ratio of 0.45 (95% CI: 0.28 to 0.75) between the higher and lower categories. It also showed that early pregnancy

physical activity was protective against GDM with odds ratio 0.76 (95%CI: 0.70 to 0.83) (48).

4.13.3 Family history of Diabetes Mellitus:

The Framingham Offspring Study, a prospective epidemiologic study of over 5,000 young adults in the USA, reported that an individual who had one or both parents with Type II DM has a lifetime risk of 30–40% and 70% for developing diabetes respectively (49).Paternal history of diabetes was not found to be significantly associated with occurrence of Diabetes Mellitus (8) (49).

Gestational diabetes mellitus is associated with family history of Diabetes. Many Retrospective and prospective studies eliciting history of diabetes among first degree relatives show that paternal history of diabetes to be significantly associated with occurrence of GDM RR 3.3 (95% CI:1.1 to 10.2),maternal history to be significantly associated with occurrence of GDM RR 3 (95% CI:1.2 to 7.3)(8).

4.13.4 Age and Ethnicity:

A population based cross sectional study done in Australia showed that the prevalence of GDM was 3.7% in women born in Australia and 11.5% in women of Asian origin. The prevalence in women born outside Australia is 41.4%. The study also found that except women born in north America all other had increased risk of developing GDM with age more than 30 ($p<0.001$)(25).

A population based cohort study done at Oslo University hospital among 759 multi ethnic women where OGTT was done on them. The South Asian women constituted 25%, Middle East women constituted 15%, others were Western European women in the study population. It was found that ethnicity was an independent factor in acquiring GDM. The South Asian women had OR 2.24 (95% CI: 1.26 to 3.97), Middle East women had OR 2.13 (95% CI: 1.12 to 4.08) (50).

A cohort study for Diabetes prevention program at George Washington University did a base line HbA1C level test for 3819 people more than 25 years of age. The results showed that the mean HbA1C levels among whites were 5.78%, among Hispanics 6%, among blacks 6.18%, American Indians 6.12% and 6% among Asians (51).

4.13.5 Diet during pre-pregnancy: A cohort study was done using Nurses' Health Study II and dietary intake was assessed periodically with semi quantitative food frequency questionnaire. The study was done to look for association between dietary calorie intake, glycemic load and incidence of GDM. It was found that dietary fibre had a continuous and inverse relationship with GDM. Every 10 gram / day increase in fibre per day led to 26% reduction in risk of GDM.

The glycemic load in diet was positively related to GDM with 1.61 times higher than the lowest quintile (95% CI: 1.02 to 2.53, p value for trend 0.03). There was a risk of 2.15 times in incidence of GDM on consuming low fibre and high glycemic diet (95% CI: 1.04 to 4.29) (52).

4.13.6 Decreased sleep duration and risk of GDM:

Recent evidences had shown that decreased sleep duration caused increased insulin resistance and decreased insulin sensitivity and are risk factors for GDM (53-55).

A cohort study was done on women in early pregnancy to find the association between sleep hours and GDM. It was found that women who sleep less than or equal to four hours are having 5.59 times (95% CI 1.31 to 23.69) risk of having GDM than those who sleep more than nine hours per night. The lean women with BMI less than 25 had RR 3.23 (95% CI 0.34 to 30.41), overweight women with BMI more than or equal to 25 had RR 9.83 (95% CI 1.12 to 86.32) (54).

Another study to find association between sleep and GDM showed that with every one hour of reduced sleep time was associated with 4% increase in glucose levels in blood. After adjustment for BMI it was found that disordered breathing during was associated with three times risk of acquiring GDM OR 3.0 (95 % CI: 1.2 TO 7.4) (55). Those who had short sleep had 3.4 times risk of GDM OR 3.4 (95% CI: 1.3 to 8.7) than those who had less than seven hours of sleep. The study also explored that frequent snoring during sleep was associated 3.4 times with GDM OR 3.4 (95% CI: 1.3 to 8.8) than those who did not snore (55). A prospective cohort study done on nulliparous women also explores significant association between snoring and GDM after adjusting for the confounding factors (53).

The pathophysiology behind inverse relationship between sleep and GDM was first noted by Spiegel et al who found that the glucose tolerance, acute insulin response to glucose, effectiveness of glucose, sensitivity to insulin, disposition index are significantly differing

between sleep deprived population and reference population. It was found that the glucose tolerance levels among sleep deprived was 40% lower and insulin response to glucose was 30% lower than the reference population (56).

4.14 Effects of dietary interventions on outcomes of GDM:

The interventions examined by various studies apart from pharmacological management are life style modification, dietary calorie/ carbohydrate restriction, physical activity etc.

A Meta analyses was done on 1170 studies including 9 randomized controlled trials (RCT)which had interventions like life style modification, low glycemic index foods, low calorie food intake, low carbohydrate food intake on GDM women. It was found from the study that low glycemic index diet reduced percentage of women who used insulin with RR 0.76 (95% CI: 0.59 to 0.98) (57) when compared with women who were on controlled diet. There was a decrease in birth weight of newborns of mothers who consumed low glycemic diet with mean weight difference – 161.9g (95% CI: -246.4 to -77.4) ($p < 0.001$). There was no significant difference in maternal and newborn outcomes in women taking total calorie restriction and low carbohydrate diet (57).

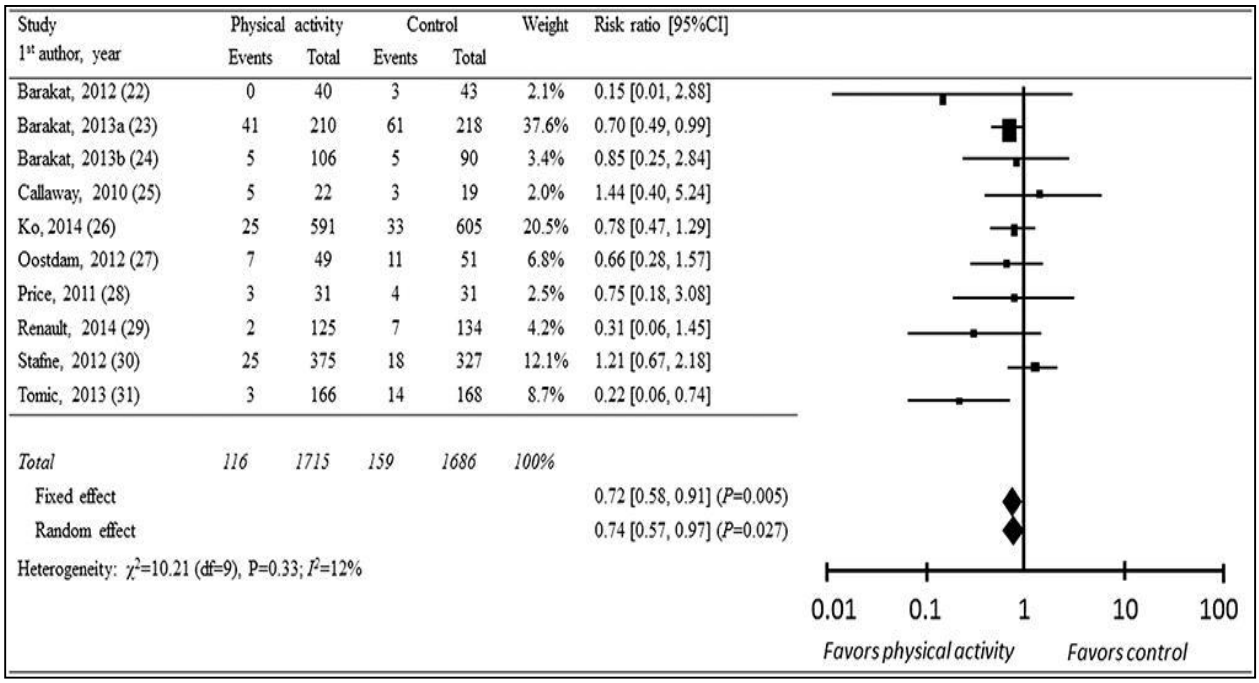
4.15 Effects of physical activity interventions on women with GDM:

As discussed before there is an inverse association between high pre pregnancy physical activity levels and GDM (46, 47). Similarly physical activity had been proven to be decrease the risk of GDM during pregnancy if used as an intervention. Various studies

done with measurement of physical activity and GDM showed that physical activity was a protective against development of GDM. A Meta-analysis done on 469 studies, involved 3401 participants which had physical activity apart from dietary restriction as intervention and development of GDM as outcomes. This Meta-analysis included only RCTs with pregnant women who did not have GDM at base line

The effect of physical activity on GDM from the Meta analysis is illustrated by the following Figure 4.5

Figure: 4.7: Forest Plot of Meta analyses on Physical activity and GDM



Source: Ovid technologies Inc: Source ID 68771

It was found that there was 28% reduction in risk of GDM in intervention group than control group and the RR was 0.72 (95% CI: 0.58 to 0.91) (58). It was concluded from the analysis that physical activity provided a protective effect against development of GDM.

4.16 GDM model for prevention of Type II Diabetes Mellitus:

Among people with Type II Diabetes Mellitus 30% could be due to GDM during pregnancy. GDM is now being recognized as an opportunity to primarily prevent Type II DM and its complications. A new mathematical model has been developed which provides estimated costs of screening GDM and costs of lifestyle interventions to prevent GDM and compares the costs with the DALYs averted by not doing a universal screening. This model was tested in five countries including India. It was found that there was a net saving of $ 78 per woman on performance of universal screening and post-partum lifestyle management which was lower on comparison to Israel. The DALY averted was 2.33 for India and the cost of averting one DALY was $11.32(59). It was concluded that the GDM model of universal screening for GDM and post-partum lifestyle management had a cost saving and good cost effectiveness ratio over no screening and no post-partum intervention.

5. Methodology

5.1 Study setting:

This study was carried out at the Rural Health Centre (CHAD Hospital) run by the Department of Community Health, Christian Medical College, Vellore. This hospital caters to health needs of Kaniyambadi block which has a population of 1, 20,000. Apart from Kaniyambadi block, people from neighboring towns of Ranipet, Arni and Polur come to CHAD hospital for health care. The hospital is located at a strategic location at Bagayam and is well connected by transport networks.

5.2 Study period:

The recruitment and patient home visits started in February 2015 and ended in July 2015.

5.3 Sample size calculation:

For estimate of prevalence of GDM, the sample size was calculated with the formula

$4\ PQ/d^2$.

The prevalence of GDM as obtained from various studies done in Tamilnadu varies between14% to 23%. Hence a prevalence of 15% was taken for calculating sample size.

P=prevalence of GDM from previous studies, Q = (1-P), d = 20% relative precision.

The sample size for estimating Gestational Diabetes was arrived as

4x15x85/3x3 = 567.

Therefore n=567 antenatal women had to be screened for GDM with Oral Glucose Tolerance Test (OGTT) to estimate the Prevalence of GDM.

5.4 Inclusion criteria:

All ante natal women attending the general ANC OPD of the Rural Health Centre (Ante Natal Care – Out Patient Department) irrespective of their obstetric score.

5.5 Exclusion criteria:

1. Women already known to have Diabetes Mellitus Type I and Type II.

2. Women on drugs like steroids, olanzapine, phenytoin, thiazides.

3. Women with auto immune diseases.

5.6 Study design:

The design used was a cross sectional study design. Antenatal women attending the Outpatient departments (OPD) for ante natal care between were recruited into the study after obtaining informed consent and were given a date for Oral Glucose Tolerance Test (OGTT). The women recruited into the study had varying gestational ages up to 28 completed weeks. OGTTs were scheduled to be performed at the laboratory run by the CHAD Hospital between 24 to 28 weeks of gestational age. Detailed instructions regarding the test were given to the women at recruitment and also 2 days before scheduled testing through phone calls.

5.7 Laboratory Diagnosis of GDM:

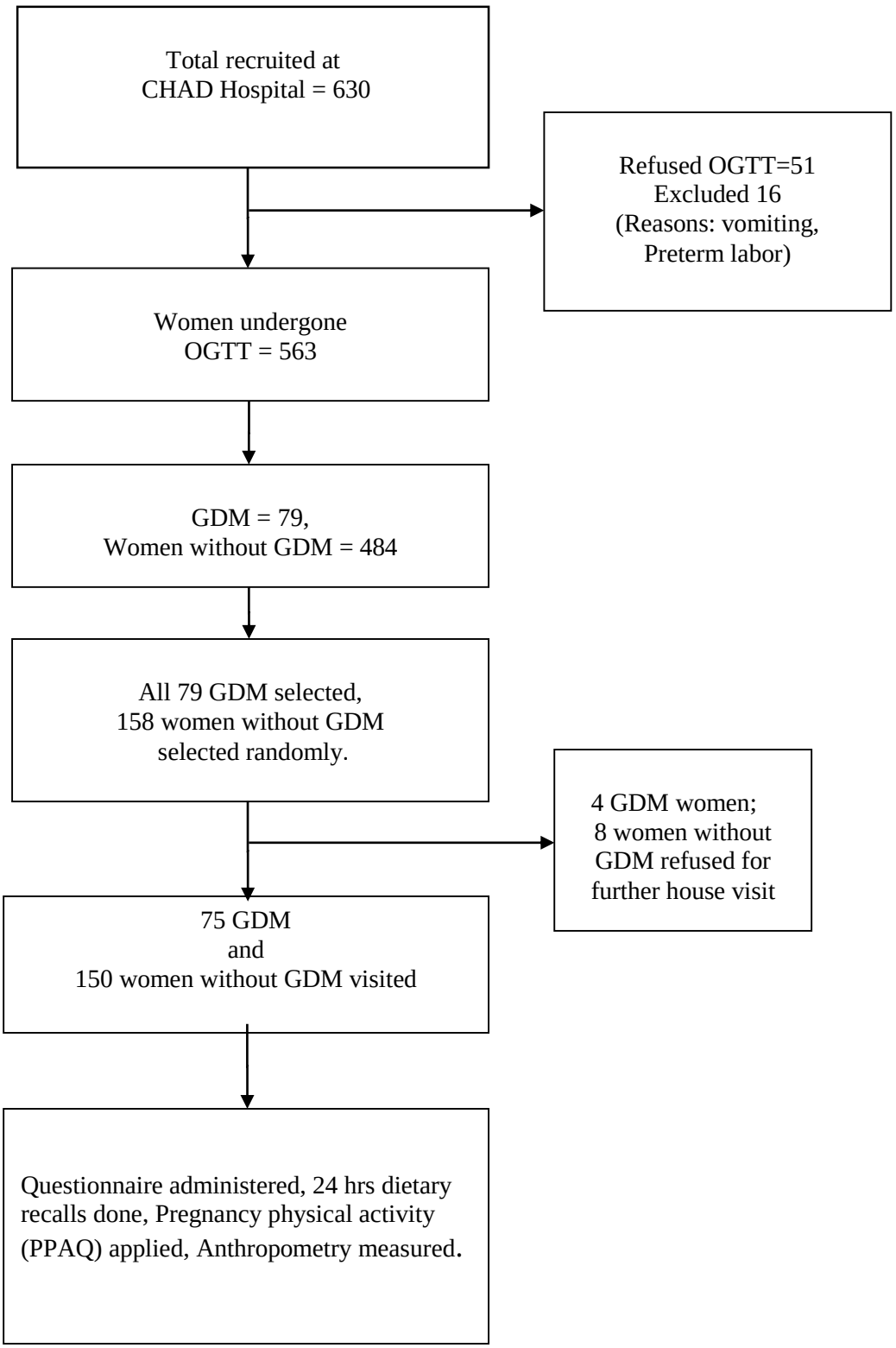
The lab attached to the rural health centre is validated by Christian Medical College Quality control cell regularly. Blood glucose levels were analyzed by the GOD-POD method (Glucose Oxidase Peroxidase method).OGTT was performed with 75 grams of glucose dissolved in water and lime added to it for better taste. Blood samples were drawn at

fasting, 1 hrs. and 2 hrs. following oral glucose intake. Women who vomited after intake of 75 grams of glucose or at any time before the completion of the test were excluded.

The total numbers of women recruited were 630. Out of 630 women recruited 51 women refused to participate in the study further, 16 were excluded due to vomiting and one subject had preterm labor before the scheduled date for OGTT. Finally 563 of the 630 antenatal women were screened for GDM with OGTTs. Among them 79 women were diagnosed to have GDM and 484 women had no GDM based on the IADPSG criteria.

For studying the factors associated with GDM, all the79 women who were diagnosed to have GDM and a sub set of 158 women who did not have GDM were randomly selected for further home visits. The Principal Investigator was blinded to the GDM status of the selected subjects. A total of 12 women (4 GDM and 8 Non GDM) refused further participation in the study. A total of 75 GDM and 150 women without GDM women were visited at their homes. Recruitment and follow up of subjects has been illustrated in Figure 5.1.

Figure: 5.1: Flow chart depicting methodology of the study:



5.8 Data collection:

Subject identifiers including name, hospital number, date of birth, address and contact numbers were collected from the women who were recruited in the study. Informed consent was obtained for OGTT and home visit at the time of recruitment. The women were contacted before the home visits, their convenient date and time was collected and home visits were made. The women were visited within two weeks of OGTT. At the home visit, the study participant's name, hospital number, address, obstetric details, family history of diabetes were collected and questionnaire on physical activity (PPAQ) administered. Dietary assessment was done using the 24 hour recall method.

5.9 Study tool:

A semi structured questionnaire was used to collect basic information of the study participant, obstetric details like last menstrual period, expected date of confinement, previous pregnancy details, previous delivery details, OGTT date, gestational age at OGTT and socio economic details like education, occupation, family income. For dietary assessment 24 hrs dietary recall method was used. The questionnaire also had components of body measurements like height, weight, biceps, triceps, subscapular skin fold thicknesses and mid upper arm circumference.

5.9.1 Assessment of dietary intake:

The pregnant woman's dietary intake was assessed by last 24 hour dietary recall method. The woman was asked about the food they consumed the previous day from morning to bed time. Standard cups, glasses, ladles, spoons were used to assess the actual amount of food consumed by the pregnant women. Then the calories present in the raw ingredients and food items were calculated using the database of "Nutritive Value of Indian Foods" by the National Institute of Nutrition (NIN) (60). The nutrients from the ready-made foods like biscuits and other packaged food items were calculated from the information given by the manufacturers.

5.9.2 Assessment of physical activity:

Physical activity levels during pregnancy were assessed by a semi quantitative questionnaire called Pregnancy Physical Activity Questionnaire (PPAQ) (61). Two questions which were culturally not applicable were replaced by applicable ones with same intensity activity. It contains 32 questions each having five answer options. The questionnaire was translated into Tamil and back translated into English and validated. Participants had to respond the time spent on each activity. There were 13 questions on household/care giving activity, 5 on occupation activity, and 8 on sports/exercise activity, 3 on transportation activity and 3 on inactivity. The questionnaire was applied for the current

trimester of the pregnancy at the time of interview. Each question was read out to the patient in Tamil and the response was marked in the answer options.

The answers had a fixed score which was multiplied with seven and again multiplied with intensity scores of that particular question to arrive at Metabolic Equivalents on Testing MET hrs/week for that particular question as per the coding guidelines provided in the tool. Then all the scores were added together to arrive at total activity in MET hrs per week. Finally, each woman in the study had scores for sedentary activity, light activity, moderate activity, vigorous activity, occupational activity and total activity in MET hrs per week.

5.9.3Anthropometric measurements:

The study participants height and weight were measured using a stadiometer and weighing scale. Height was measured to nearest centimeter and weight measured to nearest 100 grams. Skin fold thickness measurement calipers was used to measure Biceps, Triceps, mid upper arm circumference to the nearest millimeters. Mid upper arm circumference was measured with a measuring tape in centimeters. All the measurements were taken twice and the mean of two readings was considered as the final measurement.

5.9.3.1 Measurement of mid upper arm circumference:

The mid upper arm circumference was measured with inch tape at the midpoint between head of the humerus and tip of the elbow. It was measure in centimeters and the

circumference was marked on the arm with a marker. The measurements were made twice and mean score was considered as final.

5.9.3.2 Biceps skin fold thickness measurement:

The biceps skin fold thickness was measured with the woman standing in a relaxed position with arms at sides. The site of measurement was identified on the anterior surface of the upper arm in line with the mid upper arm point and parallel to long axis. The thumb and index finger was used to grasp the skin fold and the skin was rolled from side to side to remove muscle. The skin fold thickness was measured with calibrated Harpenden's calipers placed 90 degree to the skin, one centimeter distal to the marked site and the measurement taken after two seconds. The reading was measured in millimeters and average of the two readings was taken.

5.9.3.3 Triceps skin fold thickness measurement:

The triceps skin fold thickness was measured with the woman standing in relaxed position with arms at sides and at slightly pronated. The measurement was taken by standing behind her. The site of measurement was marked at the intersection of mid upper arm circumference line on the posterior surface of the arm. The thumb and index finger was used to grasp the skin fold and the skin was rolled from side to side to remove muscle. The skin fold thickness was measured with calibrated Harpenden's calipers placed 90 degree to the skin, one centimeter distal to the marked site and the measurement taken after two

seconds. Biceps and triceps skin fold measurements were alternated to allow time for tissue decompression. Two readings were taken in millimeters and the average was considered.

5.9.3.4 Sub scapular skin fold thickness measurement:

The sub scapular skin fold thickness was measured by standing behind the woman. With the woman standing in a relaxed position and arms at her sides, the inferior angle of scapula was palpated. The site of measurement was 2cm and 45 degree inferior and oblique to the angle of scapula. The thumb and index finger was used to grasp the skin fold and the skin was rolled from side to side to remove muscle. The skin fold thickness was measured with calibrated Harpenden's calipers placed 90 degree to the skin, one centimeter distal to the marked site and the measurement taken after two seconds. Two readings were taken in millimeters and the average was considered.

The skin fold measurements were used to calculate the body fat percentage with the formula mentioned in Figure 4.3 (literature review section)

The Body Mass Index (BMI) is given by weight in kilograms / (height in meters^2) (45). The standard BMI cut off for obesity according to WHO guidelines is 30. As per the consensus statement, the BMI of more than 25 was taken as the cut off point for obesity for Indian populations (62).

5.9.4 Data entry and analysis:

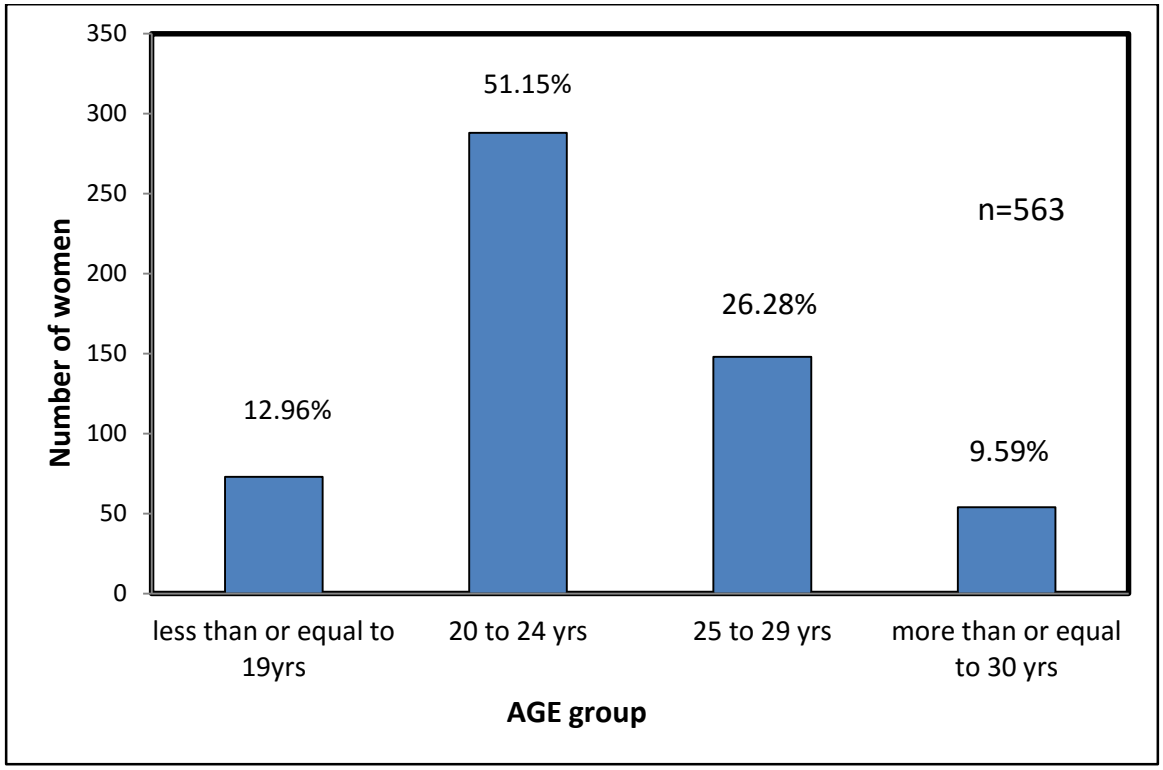
The data were entered into Epi data software version 3.1 and analysis done using SPSS software version 18.0.The demographic details and the descriptive statistics were calculated by using mean or median along with standard deviation. The study group was classified into GDM group and women without GDM according to the IADPSG criteria of diagnosis of Gestational diabetes mellitus. Descriptive analysis of study population on education, occupation, socio economic status, obstetric details was done. Bivariate analysis was done between associated factors like age, education, occupation, socio economic status, family history of Diabetes, physical activity, BMI, Body fat percentage between GDM and women without GDM. The mean differences between the groups were estimated by using chi square test of significance. Correlation was done between continuous variables and Pearson correlation co efficient estimated. Multivariate analysis by logistic regression was done with risk factors which proved to be significantly associated ($p<0.05$) with the outcome

6. Results

6.1 Demographic characteristics of the study population:

A total of 563 antenatal women attending antenatal OPD at CHAD Hospital were screened for GDM by OGTT. The age distribution of the study population is shown in the Figure 6.1.

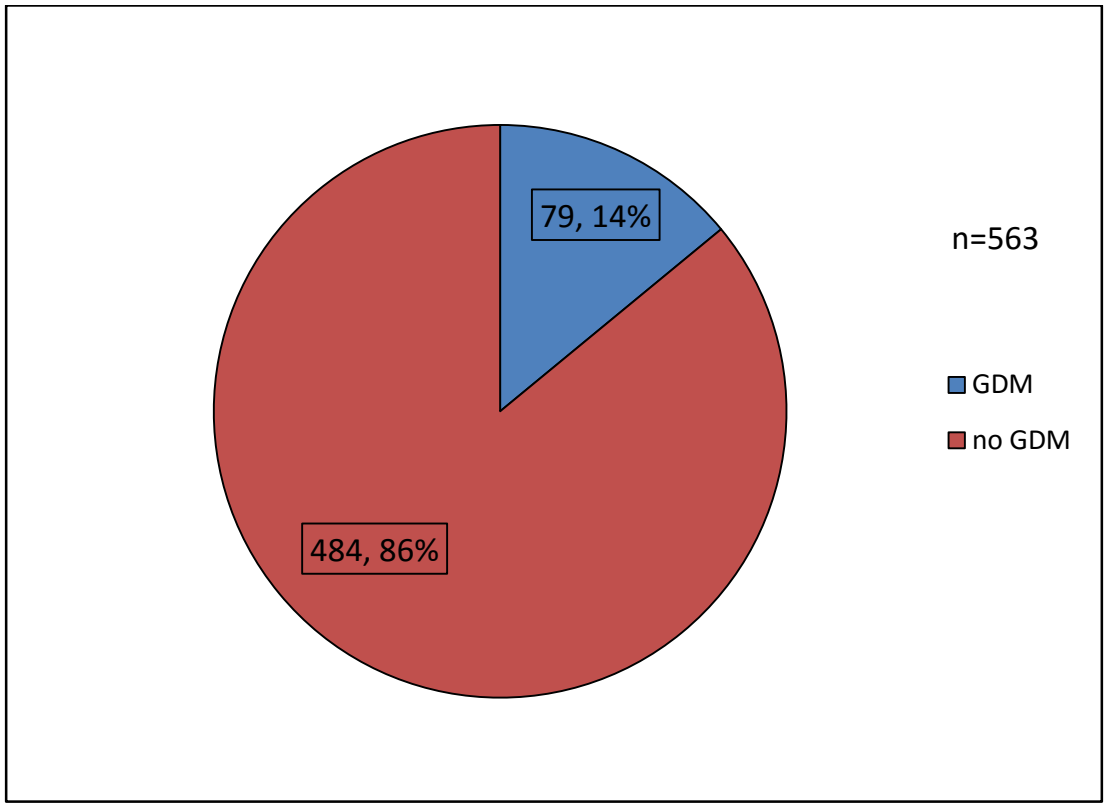
Figure 6.1: Age distribution of study population



The minimum age was 16 yrs. and maximum age was 38 yrs. The mean age of the screened population was 23.72 yrs; median was 23 yrs and standard deviation 3.84 yrs.

6.2. Prevalence of Gestational Diabetes mellitus among the study population:

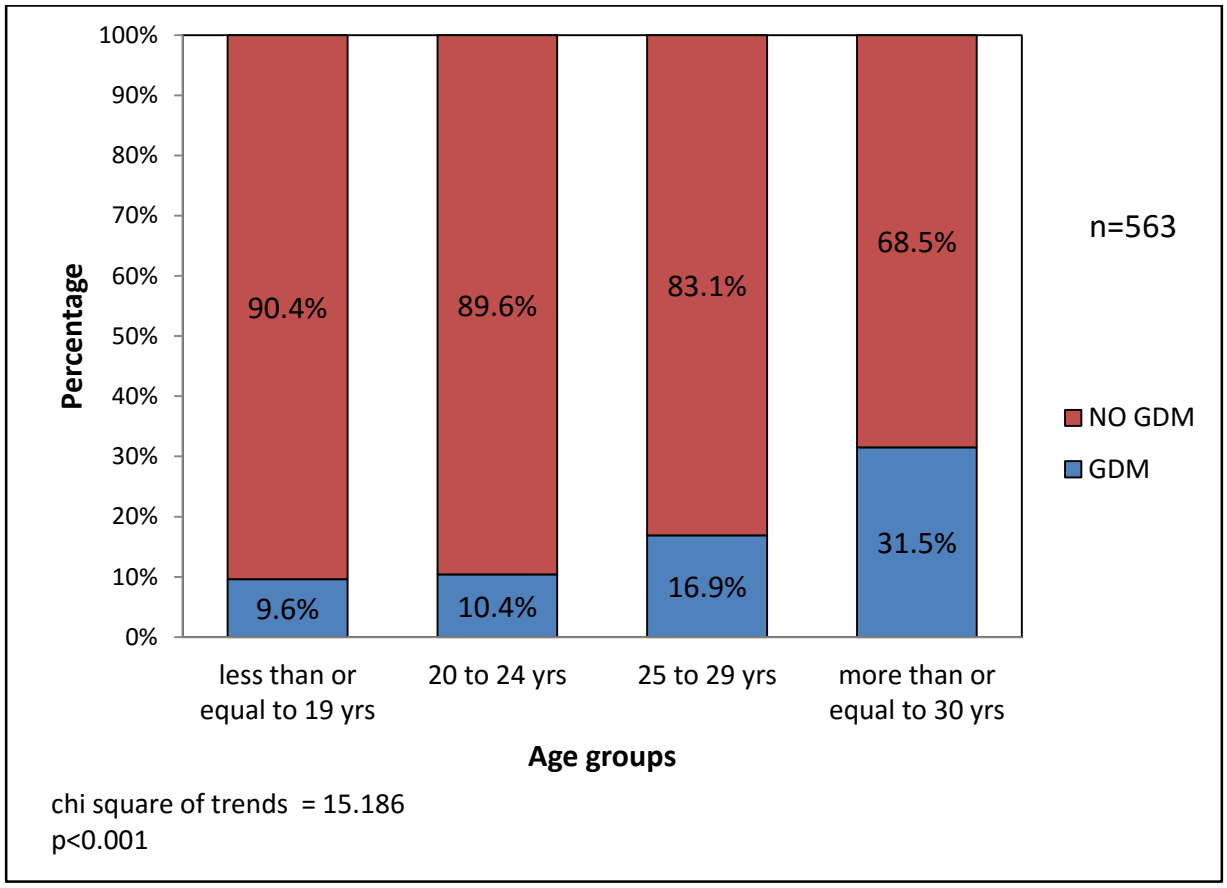
Figure 6.2: Prevalence of GDM among antenatal women:



The prevalence of Gestational diabetes mellitus based on IADPSG criterion of OGTT ≥92/180/153mg/dl among the study population of 563 was 14.0% (95% CI: 11.3% to 16.7%).

6.3 Age specific prevalence of GDM among antenatal women:

Figure: 6.3: Age specific prevalence of GDM among antenatal women



An increasing prevalence of GDM with age was noted among the study participants. The age specific prevalence of GDM was found to be 9.6% among antenatal women less than or equal to 19 yrs of age (95% CI: 2.6% to 15.4%), 10.4% in age group 20 to 24 yrs (95% CI: 6.7% to 13.3%), 16.9% in age group 25 to 29 yrs (95% CI: 11% to 21%) and 31.5% in age group more than or equal to 30 years (18.9% to 43.1%). This increasing trend of prevalence with age was statistically significant (Chi square = 15.18; p<0.001).

6.4: Socio demographic characteristics:

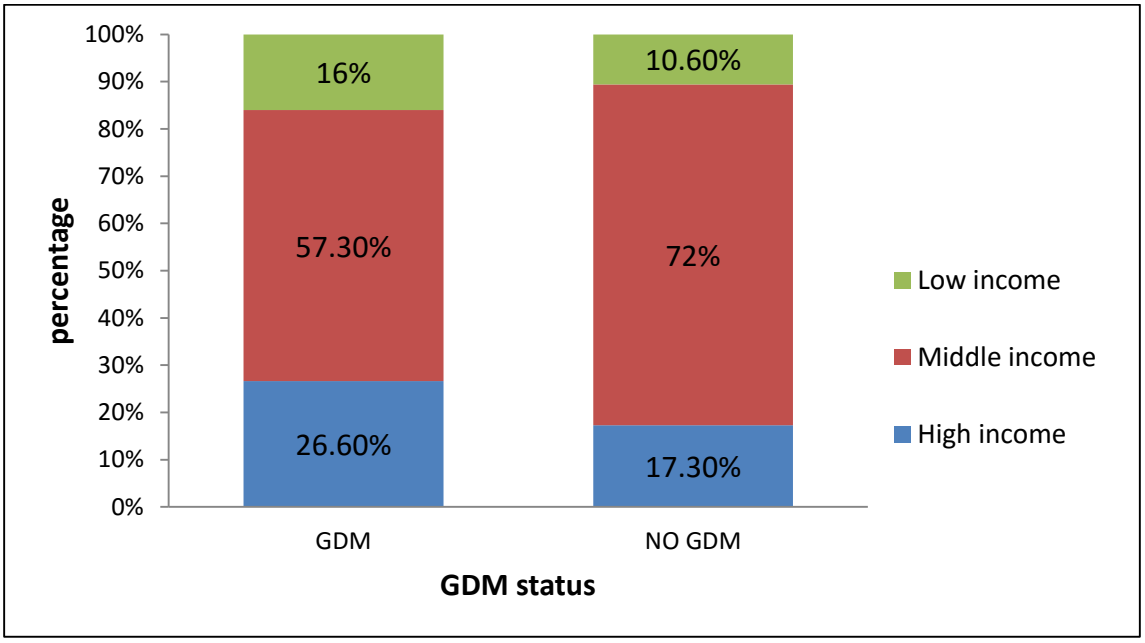
Table: 6.1: Socio demographic characteristics of study population

		GDM n=75	NO GDM n=150	p value
Education level	College	19(25.3%)	27(18%)	0.680
	Higher secondary	45(60%)	103(68.7%)	
	Up to high school	11(14.6%)	20(13.3%)	
Occupation	Housewife	71(94.7%)	141(94%)	0.895
	Professional /semi professional	0(0%)	4(2.6%)	
	Clerical/agriculture/shop owning	2(2.7%)	2(1.3%)	
	Semiskilled/student	2(2.6%)	3(2%)	
Socio economic status	High	20(26.6%)	26(17.3%)	0.597
	Middle	43(57.3%)	108(72%)	
	Low	12(16%)	16(10.6%)	

In the GDM group, 25.3% had studied up to college level, 60% had studied up to higher secondary level of education, and 14.6% had studied up to high school. Among women without GDM, 18% had studied up to college level, 68.7% had studied up to higher secondary level and 13.3% up to high school level. There was no significant difference between both the groups in education levels (p value=0.680). In the GDM group 94.7% were house wives, 2.7% were doing clerical/agriculture/shop owning occupation and 2.6%

were either students or semi-skilled workers. There were no women in the professional, semiprofessional, skilled, unskilled occupation among the GDM group. Among the women without GDM 94% were house wives, 2.6% were professional or semiprofessionals, 1.3% were doing clerical/agriculture/shop owning occupation and2% were either college students or semi-skilled laborers. There were no skilled or unskilled laborers in the group. There was no significant difference in occupations between both the groups. The socio economic and education levels of the study population are illustrated in the Figure: 6.4

Figure: 6.4: Socio economic status of the women with and without GDM:



The GDM group had 26.6% women in high socio economic status, 57.3% in middle socio economic status and 16% in low socio economic status. The women without GDM had 17.3% women in high socio economic status, 72% in middle socio economic status and 10.6% in low socio economic status. There was no significant difference in socioeconomic levels between women with and without GDM shown in Figure 6.4

6.5 Antenatal characteristics of women with and without GDM:

Table: 6.2: Antenatal characteristics of women with and without GDM

		GDM n=75	NO GDM n=150	p value
Gravida	Primi gravida	34(45.3%)	74(49.3%)	0.384
	Gravida 2	26(34.7%)	50(33.3%)	
	Gravida 3 and above	15(20%)	26(17.33%)	
Parity	Para 0	40(53.3%)	85(56.7%)	0.417
	Para 1	27(36%)	51(34%)	
	Para 2 and above	8(10.6%)	14(9.3%)	
Previous preterm delivery(n=117)*	yes	1(2.4%)	3(3.9%)	0.672
	no	40 (97.6%)	73 (96.1%)	
Presence of bad obstetric** history(n=117)*	Yes	3(7.3%)	3(3.9%)	0.435
	no	38 (92.7%)	73 (96.1%)	

*includes women with second pregnancy and above only

** Presence of stillbirths/intra uterine deaths/early neonatal death/congenital anomalies

Among the women with GDM 45.3% were Primigravida, 34.7% were second gravida and 20% were third gravida and above. Among women without GDM 49.3% were Primigravida, 33.3% were second gravida and 17.33% were third gravida and above. There was no significant difference between both the groups regarding present pregnancy status. Among the GDM group women 53.3% were nulliparous, 36% were primiparous and 10.6%

were multiparous and above. Among the women without GDM 56.7% were nulliparous, 34% primiparous and 9.3% multiparous. Excluding the Primigravida women there were 2.4% women with previous preterm delivery and 7.3% women with bad obstetric history (history of intra uterine death, still birth, early neonatal death, congenital anomaly) among GDM group women. There was no significant difference between both the groups with respect to previous preterm delivery (p value=0.672) or past bad obstetric history (p value= 0.435).

6.6 Family history of Diabetes:

Table: 6.3: Family history of Diabetes mellitus in women with and without GDM

History of Diabetes mellitus(DM)		GDM(n=75) n (%)	NO GDM(n=150) n (%)	p value
Maternal history of DM	Yes	18 (24%)	10(6.7%)	<0.001*
	No	57 (76%)	140 (93.3%)	
Paternal history of DM	Yes	15(20%)	16(10.7%)	0.056
	No	60 (80%)	134 (89.3%)	
Any parent DM	Yes	28(37.3%)	22(14.7%)	<0.001*
	No	47 (62.7%)	128 (85.3%)	
Both parents DM	Yes	5(6.7%)	4(2.7%)	0.150
	No	70 (93.3%)	146 (97.3%)	

*statistically significant

In the GDM group 24% of women had maternal history of diabetes mellitus as compared to 6.7% among women without GDM. This difference was statistically significant by Chi-square test for proportions (p value<0.001).There were 20% women with paternal history

of diabetes among women with GDM and 10.7% among women without GDM. . In the GDM group 37.3% women had at least one parent to be diabetic and among women without GDM 14.7% had at least one parent to be diabetic. 6.7% and 2.7% had history of diabetes in both parents among women with GDM and without GDM respectively. The GDM group had higher proportions of family history of diabetes than women without GDM.

6.7 Nutritional anthropometry:

Table: 6.4: Nutritional anthropometry of women with GDM and without GDM

Anthropometry	GDM (n=75) Mean(SD)	NO GDM (n=150) Mean(SD)	Mean difference	't' test value	p value
Height (cm)	152.43(6.43)	154.10(5.72)	1.673	1.98	0.049
Weight(kg)	57.47(11.44)	53.07(10.63)	4.399	2.85	0.005*
BMI	24.70(4.44)	22.30(4.03)	2.401	4.069	<0.001*

*statistically significant

The anthropometric measurements taken include height, weight, biceps skin fold thickness, triceps skin fold thickness, subscapular skin fold thickness, mid upper arm circumference. The mean height in women of GDM group was 152.43 cm (SD 6.43) and the mean height among women without GDM was 154.10 cm (SD 5.72). There was no statistically significant difference between both the groups on student t test. The mean weight was 57.47 kg (SD 11.44) in the GDM group and 53.07 kg (SD 10.63) among women without GDM and there was statistically significant difference (student t test p value <0.005). The

mean BMI in GDM group women was 24.70 (SD 4.44) and among women without GDM was 22.30 (SD 4.03). There was a statistically significant (student t test p value <0.001) as shown in Table 6.4.

The mean Biceps skin fold thickness among GDM group was 11.99 (SD 5.56) and 9.78 (SD 5.04) among women without GDM Table 6.5. There was a statistical significant difference between both the groups on 't' test with p value 0.003. The mean of Triceps skin fold thickness among GDM group was 19.46 (SD 4.81) and 16.77 (SD 5.32) among women without GDM. There was statistically significant difference between both the groups on 't' test with p value < 0.001.

The mean Subscapular skin fold thickness among GDM group was 15.20 (SD 5.31) and 13.34 (SD 4.66) among women without GDM. There was a statistically significant difference of means of both the groups on 't' test with p value 0.008.The mean mid upper arm circumference among GDM group was 26.69 (SD 3.16) and 25.35 (SD 3.23) among women without GDM. There was a statistically significant difference of means of both the groups on 't' test with p value 0.004.

The mean body fat percentage of GDM group was 26.56 (SD 4.78) and 24(SD 4.74) among women without GDM. There was a statistically significant difference of means of both groups on 't' test with p value <0.001. The significant differences between GDM group and women without GDM are given in the Table: 6.5

Table: 6.5: Skin Fold measurements of the study population

Anthropometry	GDM (n=75) Mean(SD)	NO GDM (n=150) Mean(SD)	Mean difference	't' test value	p value
Biceps skin fold thickness(mm)	11.99(5.56)	9.78(5.04)	2.209	2.99	0.003*
Triceps skin fold thickness(mm)	19.46(4.81)	16.77(5.32)	2.686	3.68	<0.001*
Subscapular skin fold thickness (mm)	15.20(5.31)	13.34(4.66)	1.858	2.68	0.008*
Mid upper arm circumference (cm)	26.69(3.16)	25.35(3.23)	1.337	2.94	0.004*
Body fat%	26.56(4.78)	24(4.74)	2.559	3.80	<0.001*

*statistically significant

6.8 Physical activity:

The physical activity levels of GDM group and women without GDM were estimated in MET hrs per week based on PPAQ questionnaire. The physical activity done by the populations were grouped into different categories as performing sedentary activity, light activity, moderate activity, vigorous activity, household/care giving activity according to the intensity of the work done as per the PPAQ questionnaire. The mean MET hrs/wk. of moderate activity was 20.18 among GDM group and 24.23 among women without GDM. Except light activity all the other types of activities had the mean activity score more among women without GDM than GDM group meaning that women without GDM are physically more active than GDM group.

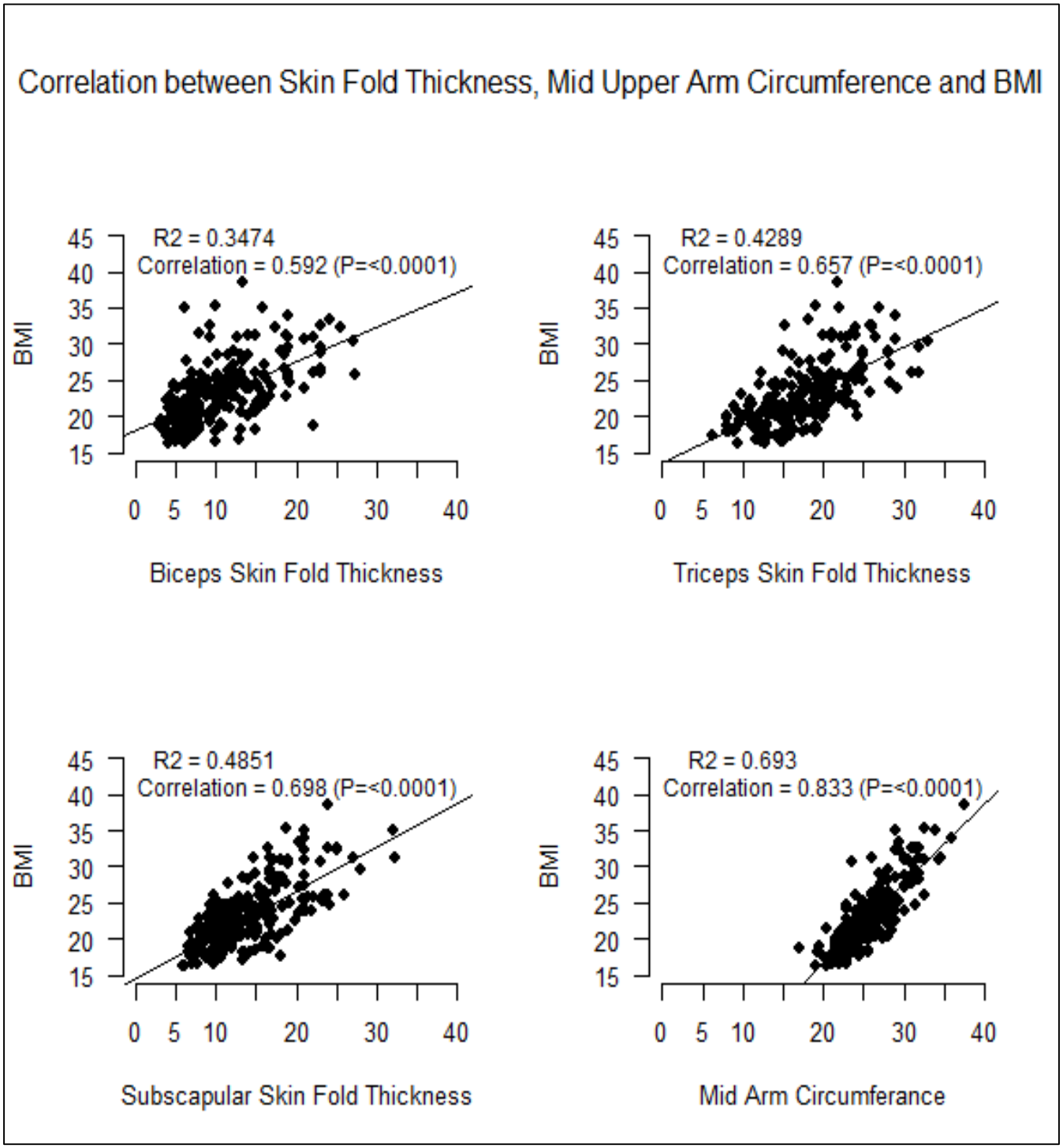
Table: 6.6: Physical activity pattern in women with and without GDM:

Physical activity	GDM (n=75) Mean(SD)	NO GDM (n=150) Mean(SD)	Mean difference	't' test value	p value
Sedentary activity (MET hrs/wk.)	31.51(25.41)	35.01(27.08)	3.496	0.93	0.353
Light activity (MET hrs/wk.)	66.79(31.09)	62.79(27.12)	4.000	0.99	0.322
Moderate activity (MET hrs/wk.)	20.18(21.42)	24.23(25.93)	4.054	1.16	0.244
Vigorous activity (MET hrs/wk.)	2.07(5.20)	2.31(6.08)	0.240	0.29	0.770
Household/care giving activity	70.12(30.48)	73.44(35.80)	3.323	0.68	0.492
Occupational activity (MET hrs/wk.)	5.58(23.39)	7.15(25.55)	1.570	0.44	0.656
Total activity (MET hrs/wk.)	115.28(43.21)	118.83(43.21)	3.545	0.58	0.562

On statistical analysis there was no significant difference between the mean activities of both the groups on 't' test.

6.9 Correlation between skin fold thickness and BMI:

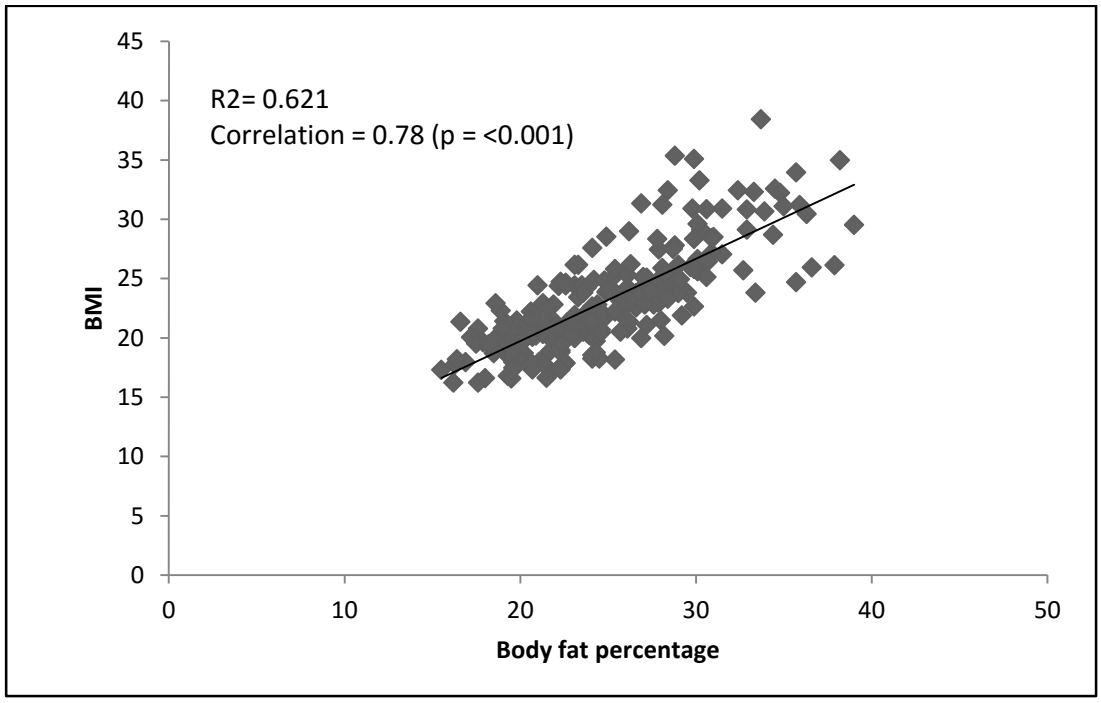
Figure: 6.5 Correlation between BMI and skin fold thickness, mid upper arm circumference.



There was a positive significant correlation between skin fold thicknesses, mid upper arm circumference and BMI. The Pearson correlation co efficient was 0.59 (p value<0.0001) for Biceps skin fold thickness and BMI, 0.65 (p value<0.0001) for Triceps skin fold thickness, 0.69 (p value <0.0001) for subscapular skin fold thickness and BMI and 0.83 (p value <0.0001) for mid upper arm circumference and BMI.

6.10 Correlation between body fat percentage and BMI:

Figure: 6.6: Correlation between Body fat percentage and BMI



The body fat percentage was calculated from the skin fold measurements using the formula given in Figure 4.3. The minimum body fat 15.5% and maximum was 39% and the mean body fat percentage among the study population was 24.8% and SD 4.90.The scatter plot representing body fat percentage in x axis and BMI in y axis is given by the figure 6.5.

There was a positive correlation between body fat percentage and BMI. The Pearson correlation co-efficient value was 0.78 (p value<0.001) and $r^2 = 0.621$.

6.11 Dietary calorie intake of women with and without GDM:

Table: 6.7: Dietary energy intake of women with GDM and without GDM

24 hrs dietary recall	GDM (n=75) Mean (SD)	NO GDM (n=150) Mean (SD)	Mean difference	't' test value	p value
Average Calorie intake/day	2042.30 (597.08)	2323.63 (626.24)	281.33	3.22	0.001*

*statistically significant

The mean dietary calorie intake of women with GDM and without GDM was 2042.30 and 2323.63 respectively. The group without GDM on an average consumed an excess of 281 kilo calories which was statistically significant as indicated by the 't' test with

p value= 0.001

6.12 Factors associated with GDM:

Table: 6.8: Association of Demographic factors with GDM

		GDM (n=75) n(%)	No GDM (n=150) n(%)	OR (95% CI)	Chi square p value
Age	More than 23 yrs	45 (40.9%)	65 (59.1%)	1.96 (1.11 to 3.44)	0.018*
	Less than 23 yrs	30 (26.1%)	85 (73.9%)		
Education	Higher secondary and above	64 (33%)	130 (67%)	0.89 (0.40 to 1.98)	0.78
	Higher secondary and below	11 (35.5%)	20 (64.5%)		
Occupation	House wife	71 (33.5%)	141 (66.5%)	1.13 (0.33 to 3.80)	0.84
	Employed	4 (30.8%)	9 (69.2%)		
Socio economic status	High, Upper middle &Middle	63 (32%)	134 (68%)	0.62 (0.28 to 1.40)	0.25
	Upper lower & lower	12 (42.9%)	16 (57.1%)		

*Statistically significant

The associations of age, education, occupation and socio economic status were studied between GDM group and women without GDM by univariate analysis. The median age of women without GDM (23 yrs) was taken as cut off point to categorize age. The higher secondary education was taken as cut off point to classify education status. The socio economic classes of upper, upper middle and middle income groups were combined

together for classifying as high socio economic status. Among the socio demographic factors age was significantly associated with GDM OR 1.96 (95% CI: 1.11 to 3.44). The other factors like education had OR 0.89 (95% CI: 0.40 to 1.98), occupation had OR 1.13 (95% CI: 0.33 to 3.80) and socio economic status had OR 0.62 (95% CI: 0.28 to 1.40) which were not significantly associated.

6.13 Association of family history of Diabetes Mellitus and GDM:

Table: 6.9: Family history of Diabetes Mellitus and GDM:

Family history of Diabetes mellitus(DM)		GDM (n=75) n (%)	NO GDM (n=150) n(%)	OR (95% CI)	Chi square p value
Maternal history of DM	Yes	18(64.3%)	10(35.7%)	4.42 (1.92to10.16)	<0.001*
	No	57(28.9%)	140 (71.1%)		
Paternal history of DM	Yes	15(48.4%)	16(51.6%)	2.09 (0.97 to 4.51)	0.056
	No	60(30.9%)	134 (69.1%)		
Any parent DM	Yes	28(56%)	22(44%)	3.46 (1.80 to 6.64)	<0.001*
	No	47(26.9%)	128 (73.1%)		
Both parents DM	Yes	5(55.6%)	4(44.4%)	2.60 (0.67to10.01)	0.150
	no	70(32.4%)	146 (67.6%)		

*statistically significant

The maternal history of Diabetes Mellitus was present in 64.3% of women in GDM group and 35.7 % among women without GDM. The odds of developing GDM among women with a maternal history of Diabetes Mellitus was 4.42 (95% CI: 1.92 to10.16) which was statistically significant (p<0.001). Paternal history of Diabetes Mellitus was present in 48.4% of women in GDM group and 51.6% among women without GDM. The odds of developing GDM among women with paternal history of Diabetes Mellitus was 2.09 (95% CI: 0.97 TO 4.51) which was statistically not significant (p=0.056). History of diabetes in any one parent was present in 56% of women in GDM group and 44% among women without GDM. The odds of developing GDM if any one parent had history of Diabetes Mellitus was 3.46 (95% CI: 1.80 to 6.64) which was statistically significant (p<0.001). History of diabetes in both the parents was present in 55.6% women in GDM group and 44.4% among women without GDM. The odds of developing GDM if history of Diabetes Mellitus was present in both the parents was 2.60 (95% CI: 0.67 to 10.01) which was statistically not significant (p=0.150).

6.14 Association between antenatal factors and GDM

The gravida score of two was taken as cut off to categorize pregnancy. Among women with gravida score of two and above 36.6% were in GDM group and 63.4% among women without GDM. There was no statistically significant association between Gravida and GDM as indicated by the OR 0.83 (95% CI: 0.41 to 1.70). Among women who had history of pre term delivery 25% were in GDM group and 75% among women without GDM. There was no statistically significant association between previous preterm delivery and

GDM as indicated by the OR 0.60 (95%CI: 0.61 to 6.04). The association of antenatal factors with GDM is given by Table: 6.10

Table: 6.10 Association of Antenatal factors and GDM

Antenatal factors		GDM (n=75) n (%)	NO GDM (n=150) n (%)	OR (95% CI)	Chi square p value
Gravida	more than two	15 (36.6%)	26 (63.4%)	0.83 (0.41 to 1.70)	0.625
	Less than or equal to two	60 (32.6%)	124 (67.4%)		
Previous preterm delivery (n=117)*	Yes	1(25%)	3(75%)	0.60 (0.61 to 6.04)	0.668
	No	74 (33.48%)	147(66.51%)		
Presence of bad obstetric history(n=117)*	Yes	3(50%)	3(50%)	1.92 (0.37 to 9.97)	0.430
	No	72 (32.87%)	147(67.12%)		

*includes women with second pregnancy and above only

Among women who had bad obstetric history 50% were among GDM group and 50% among without GDM. There was no statistically significant association between bad obstetric history and GDM as indicated by the OR 1.92 (95% CI: 0.37 to 9.97).

6.15 Association between anthropometric measurements and GDM:

Table: 6.11: Association of various anthropometric measurements with GDM:

Anthropometry		GDM (n=75) n(%)	NO GDM (n=150) n(%)	OR (95% CI)	Chi square p value
Height	Less than or equal to155 cm	51 (34%)	99 (66%)	1.09 (0.60 to 1.97)	0.764
	More than 155 cm	24 (32%)	51 (68%)		
Early pregnancy Weight	More than 50 kg	48(39.3%)	74(60.7%)	1.82 (1.03 to 3.22)	0.037*
	Less than or equal to 50 kg	27(26.2%)	76(73.8%)		
Biceps SFT (Skin Fold Thickness)	More than 8mm	52(41.9%)	72(58.1%)	2.44 (1.36 to 4.40)	0.002*
	Less than or equal to 8 mm	23(22.8%)	78(77.2%)		
Triceps SFT (Skin Fold Thickness)	More than 16 mm	58(44.6%)	72(55.4%)	3.69 (1.97 to 6.92)	<0.001*
	Less than or equal to16 mm	17(17.9%)	78(82.1%)		
Subscapular SFT (Skin Fold Thickness)	More than 12.05mm	50(40%)	75(60%)	2.00 (1.12 to 3.56)	0.018*
	Less than or equal to 12.05 mm	25(25%)	75(75%)		
Mid upper arm circumference	More than 25cm	47(42%)	65(58%)	2.19 (1.24 to 3.87)	0.006*
	Less than or equal to 25 cm	28(24.8%)	85(75.2%)		

*Statistically significant

The univariate analyses of various anthropometric measurements such as height, weight, biceps skin fold thickness, triceps skin fold thickness, subscapular skin fold thickness and mid upper arm circumference is presented in Table 6.11

The median of women without GDM was used to categorize the anthropometric variables such as height, weight, biceps skin fold thickness, triceps skin fold thickness, sub scapular skin fold thickness and mid arm circumference. Among the women whose height was less than or equal to 155 cm 34% were in GDM group and 66% among women without GDM. The odds ratio OR was 1.09 (95% CI: 0.60 to 1.97) which was statistically not significant (p value=1.09). Among the women whose early pregnancy weight was more than 50 kg, 39.3% were in GDM group and 60.7% among women without GDM. Early pregnancy weight more than 50 kg was significantly associated with GDM with an OR of 1.82 (95% CI: 1.03 to 3.22) which was statistically significant (p value=0.037).

The women with biceps, triceps, and sub scapular skin fold thicknesses more than the cut off were 41.9%, 44.6%, 40% respectively in GDM group and 58.1%, 55.4%, 60% among women without GDM. The odds of developing GDM if biceps SFT more than 8 millimeter (mm) was 2.44(95% CI: 1.36 to 4.40) and was statistically significant (p=0.002), if triceps SFT more than 16 mm was 3.69(95% CI: 1.97 to 6.92) and was statistically significant (p<0.001), if sub scapular SFT more than 12.05 mm was 2.00(95% CI: 1.12 to 3.56) and was statistically significant (p=0.018).

Among the women with mid upper arm circumference more than 25cm, 42% were in GDM group and 58% among women without GDM. The odds of developing GDM if mid upper

arm circumference more than 25 cm was 2.19 (95% CI: 1.24 to 3.87) which was statistically significant (p=0.006).

6.16 Association between BMI, Body fat percentage and GDM:

Table: 6.12: BMI, Body fat percentage and association with GDM:

		GDM n=75 n(%)	**NO GDM n=150 n(%)**	**OR (95% CI)**	**Chi square p value**
BMI	More than 25	28(48.3%)	30(51.7%)	2.38 (1.28 to 4.41)	0.005*
	Less than 25	47 (28.1%)	120 (71.9%)		
Body fat	More than 23 %	60(43.5%)	78(56.5%)	3.69 (1.92 to 7.07)	<0.001*
	Less than 23%	15 (17.2 %)	72 (82.8%)		

*Statistically significant

The BMI cut off for Indians for obesity was considered more than 25 decided by the consensus statement (62). Among the women with BMI more than 25, 48.3% of women were in GDM group and 51.7% among women without GDM. The odds of developing GDM if early pregnancy BMI was more than 25 was 2.38 (95% CI: 1.28 to 4.41) and it was statistically significant (p value=0.005).

The median of body fat percentage among women without GDM was 23% and it was taken as cut off for BMI categorization. Among the women with body fat percentage more than 23percent, 43.5% were in GDM group and 56.5% among women without GDM. The odds

of developing GDM if body fat is more than 23 percent was 3.69 (95% CI: 1.92 to 7.07) which was statistically significant (p<0.001).

6.17 Association between physical activity and GDM:

Table: 6.13: Association between physical activity with GDM

Physical activity		GDM n=75 n(%)	NO GDM n=150 n(%)	OR (95% CI)	Chi square p value
Moderate activity	Less than or equal to 7.5 MET hrs/week	23(36.5%)	40 (63.5%)	1.21 (0.66 to 2.23)	0.529
	More than 7.5 MET hrs/week	52(32.1%0	110 (67.9%)		

The recommended level of physical activity during pregnancy according to ACOG guidelines is moderate activity for 30 min for most of the days per week or 5 days/week. The score of moderate activity for 30 minutes per day is 0.25. The intensity ranges from ≥3 to ≤6. The numbers of days of recommended physical activity are five days per week. Hence 0.25 x 6 x5 =7.5 MET hrs/week was the cut off used and physical activity less than 7.5 MET hrs/week was considered as a factor to study association (63).

Among the women who had physical activity less than 7.5 MET hrs/ week 36.5% were among GDM group and 63.5% were in NO GDM group. There was no significant association between low physical activity and GDM (p value =0.529).

6.18: Multivariate analysis to examine the association between potential risk factors and GDM:

Table: 6.14: Multivariate analysis of the outcome GDM and its potential risk factors using binary logistic regression (Model 1: including Body fat %)

	Un adjusted OR(CI)	Adjusted OR(CI)	Adjusted p value
Age more than 23 years	1.96 (1.11 to 3.44)	1.45(0.79 to2.65)	0.226
Presence of DM in any parent	3.46 (1.80 to 6.64)	2.65(1.34 to 5.25)*	0.005*
Moderate Physical activity of ≤ 7.5 MET hrs/wk.	1.21 (0.66 to 2.23)	1.18(0.61 to 2.26)	0.618
Body fat more than 23 percent	3.69 (1.92 to 7.07)	2.89(1.47 to 5.68)*	0.002*

*statistically significant

A multivariate analysis using binary logistic regression was performed to look at the effect of age, history of diabetes in any parent, body fat percentage and physical activity on GDM. After adjusting for various confounding factors it was found that the odds of having GDM if any one parent had diabetes was 2.65 times than without a family history of GDM (p value =0.005). And the odds of having GDM if body fat percentage was more than 23% was 2.89 times than with less than 23% body fat (p value =0.002). Both these associations were statistically significant as indicated by the 95% CI and p values.

Table: 6.15: Multivariate analysis of the outcome GDM and its potential risk factors using binary logistic regression (Model 2: including BMI)

	Un adjusted OR(CI)	Adjusted OR(CI)	Adjusted p value
Age more than 23 years	1.96 (1.11 to 3.44)	1.54(0.84 to 2.81)	0.155
Presence of DM in any parent	3.46 (1.80 to 6.64)	2.91(1.48 to 5.72)*	0.002*
Moderate Physical activity of ≤7.5 MET hrs/wk.	1.21 (0.66 to 2.23)	1.18(0.89 to 3.36)	0.613
BMI more than 25	2.38 (1.28 to 4.41)	1.73(0.61 to 2.25)	0.100

*statistically significant

A multivariate analysis using binary logistic regression was performed to look at the effect of age, history of diabetes in any parent, BMI and physical activity on GDM. After adjusting for the confounding factors it was found that the odds of having GDM if any one parent had history of diabetes was 2.91 times than without family history of DM (p value 0.002). After adjusting for other variables BMI did not have any significant association with GDM.

7. Discussion

The prevalence of Gestational Diabetes in Tamil Nadu from a community based study in rural, semi urban, urban showed the prevalence to be 9.9%, 1.3.8% and 17.8% respectively (7). In an another study done at Trichirapalli, Tamilnadu the hospital based prevalence of GDM was found out to be 23%.The study done at hospital Lucknow (6) had 41.9% prevalence of GDM which was high in comparison to previous studies done at Tamilnadu. The studies done at tertiary care centre in Haryana showed prevalence of 7.1% (5) which was less in comparison to the prevalence in south India and Tamilnadu.

In this present study, the prevalence of GDM among antenatal women attending a secondary level Rural Health Center in Vellore is 14%(11.3 to 16.7%) which is lower than the previously reported hospital based prevalence studies from Tamilnadu. The hospital based prevalence varies widely and one reason for that could be the different cut off values used to diagnose GDM. Ethnicity and diet factors could also play a role in the differing burden across regions.

In the present study the age specific prevalence was 9.6% in women under 19 years of age, 10.4% in 20 to 24 years of age, 16.9% in 25 to 29 years of age, 31.5% in more than or equal to 30 years of age. It was found that as age advanced there was a trend of increasing prevalence of GDM. This finding is similar to other reported data from a Turkish study (64), the age wise prevalence in less than 25 years was 0.7%, 2.3% in 25 to29 years, 8.2% in 30 to 34 years and 9.5% in more than 35 years of age which also shows an increasing trend. Studies done in India and Tamilnadu also show similar trend of increasing

prevalence with age. The study done in Haryana showed that age of woman more than 25 years is 3.8 times more than less than 25 years(5). In the community based study done in Tamilnadu age of woman more than 25 had adjusted odds ratio of 2.1(7) in the present study the age more than 23 years is significantly associated with GDM unadjusted OR 1.96 (95% CI: 1.11 to 3.44). These results show that age is a significant factor associated with GDM. But on multivariate analysis after adjusting for confounders, the effect of age was not found to be significant.

Most of the women in the present study were well educated. Among the women visited, 25.3% and 18% of women were educated up to college among women with GDM and without GDM respectively and 60% and 68.7% of women had up to higher secondary level of education in GDM group and among women without GDM respectively. GDM group had 14.6% of women who had equal to or less than high school level of education and women without GDM had 13.3% up to high school. There was no significant difference in education levels of both the groups which was similar to the Turkish study (64). On testing for association education was not significantly associated with GDM showing that education has no role in acquiring GDM. Universal education till high school in India and higher rates of schooling in Tamil Nadu could have contributed to this finding.

The women in the study were house wives whose occupation involved home care, child care, cooking and other household activities. Among the GDM group 94.7% were housewives and 94% were house wives among women without GDM. Similarly in the Turkish study (64) 76.92% in the GDM group and 78.60% in among women without GDM

were house wives. There was no significant association between occupation and GDM. Most of the women attending CHAD hospital from upper lower to middle socio-economic strata and a majority of them are home makers.

There were no women in class V (lower income) in Socio economic classification among the women visited. This could be because the rural health centre provided paid services for antenatal care and affordable families alone visit the centre. The socio economic status was not significantly associated with GDM.

The studies done at Turkey (64) and Tamilnadu (65) showed 30.7% and 31.7% primi gravida among GDM women whereas in the present study there was 45.3% of primi gravida among GDM women. But there was no significant association between gravida status and GDM. This could have occurred because of the smaller number of women with gravida 3 and above as in this region a two child family norm is mostly practiced.

In the present study, maternal history of Diabetes was significantly associated with GDM with OR of 4.42 (95% CI: 1.92 to10.16) with p value <0.001and it was statistically significant. But the paternal history of Diabetes was not significantly associated with GDM with OR of 2.09 (95% CI: 0.97 to 4.51) and p value 0.056. The association of family history of Diabetes in any parent is (adjusted OR) 2.65 times than those without family history (95% CI: 1.34 to 5.25). This shows that the family history of diabetes has a significant association with GDM. The genetic causes are important risk factors attributing to GDM as discussed in section 4.5 confirming the results of previous studies (8, 50)

In the present study, maternal height had no significant difference between the GDM group and women without GDM. But early pregnancy weight had significant difference between both the groups (p value= 0.005). In a similar study conducted at Lucknow there was no significant difference in height but there was significant difference in weight between both the groups (p value= 0.01) and early pregnancy weight was found to be a significant factor associated with GDM with p value 0.037 and OR 1.82 (1.03 to 3.22) (6). The pre pregnancy weight has been shown to be significantly associated with Preeclampsia and GDM was proven by various studies done previously (66). During pregnancy, the BMI of the woman naturally increases due to maternal and fetal components and hence pre pregnancy BMI is considered more reliable indicator of obesity. In a retrospective cohort study done at Slovenia, the pre pregnancy BMI was obtained from the records and the gestational weight gain, pregnancy outcomes were observed (67). It was found that GDM was associated with higher pre pregnancy BMI 27±6.1 kg/m^2 with p value <0.001 in singleton pregnancies. In the same study smaller changes in BMI was associated with GDM in twin pregnancies p value<0.001. But in the present study previous health records of BMI were not present and hence pre pregnancy body weight was substituted with early recorded weight during pregnancy. There was a significant difference between BMI of both the groups p value <0.001. The BMI calculated using the earliest recorded pregnancy weight had a significant association with GDM (p value= 0.005) and OR of 2.38(95%CI: 1.28 to 4.41). But in multivariate analysis the BMI was not significantly associated. This could be because the early pregnancy height and weight was obtained from antenatal cards

of the women and the first measurements were taken at first antenatal visit which could have been at varying gestational ages.

The physical activity during pregnancy was measured using the PPAQ. It was found that women without GDM were more physically active than GDM group in all types of activities other than light activity. However the mean difference of activity between both the groups was small t test value 0.58 (p value 0.562) and was not significant. This could be because that among all the women visited, majority were house wives and both the groups were doing similar level of activity.

The total energy intake was calculated with 24 hrs dietary recall method. It was done to assess the current dietary practices between both the groups. It was found that the GDM group consumed around 280 calories less than the women without GDM and it was statistically significant p value <0.001. The study participants were visited within two weeks of the OGTT being performed. There is a possibility that the GDM mothers became aware of their GDM status either through follow up at CHAD Hospital or through testing by the Public Health system which could have influenced their behaviors.

The body fat percentage was calculated using skin fold thickness from biceps, triceps, sub scapular and mid upper arm circumference (43). The body fat percentage was used as a substituent of BMI during pregnancy as the BMI during pregnancy is due to both maternal and fetal components. The median of women without GDM was taken as the cut off for to categorize body fat percentage. In the

present study the body fat percentage in GDM group was more than women without GDM by mean difference of 2.55% which was statistically significant (p value <0.001). The skin fold thicknesses had a positive correlation with BMI and all were statistically significant (Figure 6.4). Body fat percentage had a positive correlation with BMI with Pearson correlation co efficient 0.78 and (p value <0.001). On univariate analysis, body fat percentage was significantly associated with GDM unadjusted OR 3.69 (95% CI: 1.92 to 7.07) (p value <0.001). In multivariate analysis after adjusting for age, family history and physical activity the body fat percentage was significantly associated with GDM adjusted OR 2.89 (95% CI:1.47 to 5.68). It has been shown in previous studies that increase in truncal body fat during pregnancy was associated with 1.31 times of developing GDM (95% CI: 1.10 to 1.56) and increased weight gain was associated with GDM with adjusted OR 1.23 (95% CI: 1.04 to 1.46) (42).

After adjusting for potential confounding factors, multivariate logistic regression analyses showed that family history of DM among parents and excess body fat >23% were significantly associated with GDM. Since body fat and BMI are positively correlated BMI > 25, age, family history, physical activity were taken for analyses and body fat was excluded in model 2. It was found that early pregnancy BMI more than 25 was not significantly associated with GDM and family history of DM became more significant. Other factors like age more than 23 years and low physical activity were not significant.

8. Limitations

The study had a dropout rate of 8% and the main reasons being travel time, long distance and difficulty to undergo OGTT test with fasting. Around 2.5% of the recruited women had vomiting after administration of 75 g of glucose and had to be excluded from the study. The plan was to meet the participants at their home within one week after the GTT, but due to long distances participants were met within two to three weeks after the GTT which could have resulted in recall bias and possibility of behavioral change among women who were aware of their GDM status.

Though the principal investigator was blinded to the GDM status of the women selected for home visits, a few women in the study came back the next day for results and those with GDM were managed according to standard management of care of the hospital. The standard management care included counseling about diet calorie restriction, issue of diet chart. This procedure could have altered the dietary habits when home visit was done.

The early pregnancy height, weight information was taken from the antenatal cards of the women, which were at different gestational ages. The information could have been biased because of inter observer variability between the hospital staff who measured them and also the calibration of the instruments used.

9. Summary and Conclusions

1. The prevalence of Gestational Diabetes among pregnant women seeking antenatal care at the Rural Health Centre run by the Christian Medical College, Vellore was 14% (95% CI: 11.3% to 16.7%).
2. A significantly increasing prevalence of GDM with age was observed. The prevalence of GDM was found to be 9.6%, 10.4%, 16.9% and 31.5 % among women in age groups up to 19; 20 to 24; 25 to 29 and above 30 years respectively.
3. There was a significant positive correlation between different skin fold thicknesses and BMI.
4. There was a significant positive association between family history of Diabetes Mellitus and GDM. If any one of the parent of the pregnant woman have/had Diabetes Mellitus then there is 2.65 times risk of acquiring Diabetes during pregnancy than other women who don't have a family history of Diabetes.
5. There was no significant association between low levels of physical activity and GDM. Women who are physically less active don't have any higher risk than physically more active women in acquiring GDM.
6. There was a significant positive correlation between body fat percentage and GDM.

10. Recommendations

1. In view of the prevalence of GDM to be 14%, universal screening of GDM among pregnant women attending CHAD Hospital is recommended. Cost effectiveness studies could be done to find out difference in costs of doing a one-step screening at 24 to 28 weeks or a two-step screening.

2. In case of universal screening proving not to be cost effective, then apart from factors like family history of Diabetes, previous GDM, bad obstetric history used for selective screening early pregnancy; first visit BMI >25 or Body fat percentage >23% could be used as an additional criteria to screen for GDM.

3. Health education sessions at the hospital to include messages on importance of screening for GDM, diet and physical activity during pregnancy and special counseling sessions for women with GDM during follow up later.

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Annexure 1

Christian Medical College, Vellore
Department of Community medicine

Study title: Prevalence of Gestational Diabetes Mellitus among antenatal women attending secondary care hospital at Vellore.

Date of interview: ---------- **study ID number: ----------**

CHAD no: ----------

Name: **D.O.B :----------(dd/mm/yyyy)**

Husband's name: **AGE :----------(completed yrs)**

Address:

Participant's obstetric score: G---P---L---A---D--- /primi

L.M.P: **---------- (dd/mm/yyyy)**

Date of first ANC visit: **---------- (dd/mm/yyyy)**

Gestation age at first visit: **---------- wks**

Gestational age on the day of GTT: **---------- wks**

Does your mother have/had diabetes? **Yes/no** **if yes how many yrs? ---------- age of onset------**

Does your father have/had diabetes? **Yes/no** **if yes how many yrs? ---------- age of onset------**

Does any of your sibling has/had diabetes ? **Yes/no** **if yes how many yrs? ----------age of onset------**

previous pregnancy details

Year of pregnancy	Ges. Age at outcome in wks	Outcome (NVD/LSCS/SC/FOR)	Birth weight In kg	

Measurements

Height: ----------cm/ ----------meters
First recorded weight
in first trimester (or)
Early pregnancy weight: ---------- kg

Present weight: **i) ----------kg** **ii) ----------kg**

mean ----------kg

Skin fold thickness

Biceps: **i) ----------ii) ----------** **(mean) ---------- mm**
Triceps: **i) ----------ii) ----------** **(mean) ---------- mm**
Sub scapular: **i) ----------ii) ----------** **(mean) ---------- mm**

Mid arm circumference : i)---------- ii)---------- **(mean) ----------cm**

Socio economic status

Education (head of family):	score
1) Professional or honors	7
2) Graduate or post graduate	6
3) Intermediate or post high school diploma	5
4) High school certificate	4
5) Middle school certificate	3
6)Primary school certificate	2
7) Illiterate	1

Occupation (head of family):	score
1) Profession	10
2) Semi profession	6
3) Clerical, shop owner, farmer	5
4) Skilled worker	4
5) Semi skilled worker	3
6) Unskilled worker	2
7) Unemployed	1

Total family income per month:

1)>32,050	12
2)16020 – 32049	10
3)12020 – 16019	6
4)8010 – 12019	4
5)4810 – 8009	3
6)1601 – 4809	2
7)<1600	1

SES score: ----------

26-29=I
16-25 =II
11-15 =III
5-10 = IV
<5 = V

SES class:----------

Participant's education:
Participant's occupation:

Last 24 hrs recall of diet (regular diet at home, no occasion in the house)

Time	food	quantity	calories
Early morning			
Breakfast			
Mid morning			
Lunch			
Tea time			
Dinner			
In between snacks			
Bed time			

கர்பகால உடல் செயல்பாடுக்கான கேள்வித்தாள்

1. தேதி :.....பெயர் :.....
2. கடைசி தீட்டான தேதி .....பங்கேற்பாளர் எண் :.....
3. குழந்தை பிறப்பதற்கான தேதி :

இந்த கர்பகாலத்தில் நீங்கள் பணி / அலுவலக வேலை செய்யாத போது, எவ்வளவு நேரம் நீங்கள் வழக்கமாக செலவழிப்பீர்கள்.

4. உணவு தயாரிப்பதற்கு சமையல், உணவு பரிமாறுவது, பாத்திரம் அலம்புவது.
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

5. உட்கார்ந்தபடி உடைஉடுத்துதல், குளித்தல், உட்கார்ந்தபடி குழந்தைகளுக்கு உணவூட்டுதல்.
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

6. நின்றபடி குளித்தல்,உடை உடுத்துதல்,குழந்தைகளுக்கு உணவூட்டுதல்.
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

7. உட்கார்ந்தபடியோ அல்லது நின்றபடியோ குழந்தைகளுடன் விளையாடுதல்
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

8. குழந்தைகளுடன் நடந்தபடியோ அல்லது ஓடியோ விளையாடுதல்
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

9. குழந்தைளை தூக்கிச் செல்வது
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

10. வீட்டில் வயதானவரை கவனித்துக் கொள்வது
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

11. எழுதுவது அல்லது கம்பியூட்டரில் பணி செய்வது
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

12. தொலைகாட்சி (டிவி) அல்லது வீடியோ பார்ப்பது
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

13. உட்கார்ந்தபடி படிப்பது, அல்லது பிறருடன் போனில் பேசுவது.
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

14. செல்லப் பிராணிகளுடன் விளையாடுவது
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

15. மேலோட்டமாக சுத்தம் செய்வது (படுக்கை விரித்தல்
துணி துவைத்தல், இஸ்திரி போடுதல், ஜாமான்களை ஒதுங்க வைத்தல்)
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

16. கடைகளுக்குச் சென்று பொருட்கள் வாங்குவது (உணவு, துணிமணிகள், மற்ற பொருட்கள்)
☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

17. .வழமான சுத்தம் செய்வது (கூட்டுவது / பெருக்குவது, ஜன்னல்களை சுத்தம் செய்வது, வாக்யூம் மெஷினில் சுத்தம் செய்வது)

☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

18. செடிகளுக்கு தண்ணீர் ஊற்றுவது

☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

19. வீட்டைச்சுற்றி கூட்டுவது அல்லது வீட்டிற்கு வெளியே கூட்டுவது

☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

வெளியே செல்வது

20.பக்கத்தில் உள்ள பேருந்து நிறுத்துக்கோ, அல்லது வேலைக்கோ, மெதுவாக நடந்து செல்வது

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

21. பஸ் நிறுத்தத்திற்கோ, வேலைக்கோ வேகமாக நடந்து செல்வது (உடற் பயிற்சிக்காகவோ அல்லது வேடிக்கைகாகவோ அல்லாமல்)

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

22. கார் ஓட்டுவது அல்லது பயணிப்பது அல்லது பஸ்ஸில் பயணிப்பது

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 நேரம் அல்லது அதற்கும் மேலாக.

வேடிக்கை அல்லது உடற்பயிற்சி

23. வேடிக்கைக்காக அல்லது உடற்பயிச்சிக்காக மெதுவாக நடப்பது.

☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

24. வேடிக்கை அல்லது உடற்பயிற்சிக்காக வேகமாக நடப்பது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

25. கேளிக்கைக அல்லது உடற்பயிற்சிக்காக வேகமாக மலைமீது நடப்பது / மலை ஏறுவது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

26. ஜாக்கிங் / ஓடுவது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

27. கர்பக்காலை உடற்பயிற்சி வகுப்பில் கலந்துக்கொள்வது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

28. நீந்துவது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

29. நடனம் ஆடுவது
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

கேளிக்கை அல்லது உடற்பயிற்ச்சிக்காக நீங்கள் எவை செய்யும் பிற செயல்பாடுகள்?அவை என்ன.

30.செயல்பாடின் பெயர்:.....
☐ இல்லவே இல்லை ☐ ஒரு வாரத்திற்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு வாரத்திற்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு வாரத்திற்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

31. செய்யாதன் பெயர்.....

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

அலுவலக பணி / தன்னார்வ தொண்டு செய்பவர் / மாணவியாக இருப்பவர் பூர்த்தி செய்யவேண்டிய பகுதி

32. வேலையிலோ அல்லது வகுப்பிலோ உட்கார்ந்திருப்பது

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

33. வேலை நேரத்தில் கனமான பொருட்களை தூக்கிக்கொண்டு மெதுவாக நடப்பது அல்லது நிற்பது (1.75 கிலோ விற்கும் மேலாக

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

34. வேலை நேரத்தில் நிற்பது அல்லது மெதுவாக நடப்பது (எதையும், பொருட்களையும் தூக்காமல்)

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

35. வேலை நேரத்தில் கனமான பொருட்களை தூக்கிக் கொண்டு வேகமாக நடப்பது (1.75 கிலோ விற்கும் மேலாக)

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

36. வேலை நேரத்தில் வேகமாக நடப்பது (எந்த பொருளையும் தூக்காமல்)

☐ இல்லவே இல்லை ☐ ஒரு நாளைக்கு 1/2 மணி நேரத்திற்கும் குறைவாக
☐ ஒரு நாளைக்கு 1/2 மணி நேரம் முதல் கிட்டத்தட்ட 1 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 1 மணி நேரம் முதல் கிட்டத்தட்ட 2 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 2 மணி நேரம் முதல் கிட்டத்தட்ட 3 மணி நேரம் வரை
☐ ஒரு நாளைக்கு 3 மணி நேரம் அல்லது அதற்கும் மேலாக.

Annexure 2

Department of Community Health
Christian Medical College, Vellore

Study title: Prevalence of Gestational Diabetes Mellitus among antenatal women attending secondary care hospital at Vellore.

Study number:

Participant Information sheet

This is a request to participate in a study to assess the prevalence of Gestational Diabetes Mellitus (GDM) among pregnant women seeking care at CHAD hospital, Bagayam, Vellore. GDM is a condition of high blood glucose levels in pregnant women. High blood glucose levels during pregnancy can lead to complications like large baby, labor before term, excessive fluid in the uterus, still births etc. This study is to find out the prevalence of gestational diabetes pregnancy among pregnant patients attending this hospital and risk factors for GDM.

If you give your willingness to participate in the study you would undergo a lab blood test called Glucose tolerance test (GTT). You would be given 75 g of glucose powder mixed with a glass of water and flavored with lemon juice to drink and your blood sample would be taken 3 times. The results of this test would be disclosed 1 week later. A doctor from CHAD hospital would be visiting you at house before disclosure of results. The doctor would be asking you questions related to study like age, number of children, family history of diabetes, socio economic status, food and diet. Your height, weight, skin fold thickness would be measured. This study duration is from December 2014 to may 2015 only.

You need not pay the cost of Glucose tolerance test.
There are no major risks associated with this procedure. The injection for collecting blood may be painful. Drinking glucose solution may be slightly uncomfortable. But there are no major proven risks associated with this procedure. There is no unforeseeable risk with this procedure. We do not expect any injury related to this study and hence will not be compensating you monetarily.
If you are participating in the study you can know whether you have the condition of Gestational diabetes. If you have the condition you will be treated at CHAD hospital for the same.

The anticipated benefits to science and humankind from this study is certain management guidelines can be made regarding the management of patients having Gestational diabetes, preventive measures can be done.

The study results may be published in a medical journal but your name and personal identifiers will not be published. However your personal details may be reviewed by the people associated with the study without any additional permission. Please read the above information carefully and feel free to ask any questions you may have about this study and information given. You will be given a copy of this information sheet and you are given an opportunity to ask questions, and your questions will be answered. Your participation in this research study is voluntary. You are also free to withdraw from this at any time. Your withdrawal will not affect any of your treatment receive from our institution (CMC Vellore and CHAD hospital)

Would you like to participate in the study? Yes No

Name of the participant: Signature of the participant
Place:
Date:

Thumb Impression

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

If you have any questions about this research study or possibly, please feel free to contact:

Dr.Geetha R 9865779707 or Dr.Venkata Raghava Mohan04162284436.
email:drgeethar@cmcvellore.ac.in or Department of Community health, Christian Medical College, Vellore (tel: 0416-228420

Annexure 3

Christian Medical College, Vellore
Department of Community Health and Development
Informed Consent Form

Study title: Prevalence and Risk factors of Gestational Diabetes Mellitus among antenatal women attending a secondary care hospital in Vellore

Study number: ----------
Subject's initials: ---------- **Subject's name----------**
Date of birth/Age----------

(Subject)

(i) I confirm that I have read and understood the information sheet dated----------for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason without my medical care and legal rights being affected.

(iii)I understand that my blood sample would be collected for testing glucose levels and I would be visited at home by the investigator and measurements of my body would be undertaken. I am aware that questions would be asked regarding my health and well being

(iv) I understand that the Ethics committee and regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.

(v) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes.

(vi) I agree to participate in the above study.

Signature (or Thumb impression) of the Subject:

Date: _____/_____/_____

Signatory's Name: _____

Signature or thumb impression of witness ---------- ---------- date: ----------

Signature or thumb impression of witness ---------- ---------- date: ----------

Signature of investigator---------- date: ----------

If you have any questions about this research study, please contact Dr.Geetha R 9865779707 or my advisor, Dr. Venkata Raghava Mohan at 04162284436 Email: drgeethar@cmcvellore.ac.in or Department of Community health, Christian Medical College, Vellore (tel: 0416-2284207)

Annexure 4

கிறிக்கவ மருத்துவ கல்லூரி வேலூர்

சமூக மருத்துவத் துறை

தலைப்பு

கர்ப்பகால சக்கரை நோய் மற்றும் காரணிகள் பற்றிய ஆராய்ச்சி

ஆய்வு எண்

கலந்து கொள்ளும் ஆய்வாளர் தகவல் படிவம்

சாட் மருத்துவமனை, பாகாயம் , வேலூரில் சிகிச்சை பெறும் கர்ப்பிணி பெண்கள் மத்தியில் கர்ப்பகால சக்கரை நோய் (GDM) பாதிப்பு மதிப்பீடு செய்ய ஆய்வில் பங்கேற்க ஒரு வேண்டுகோள். இந்த மருத்துவமனையில் மருத்துவம் பெறும் கர்ப்பிணி பெண்களிடம் உள்ள நீரிழிவு பாதிப்பையும் அதன் ஆபத்து காரணிகளையும் கண்டுபிடிக்க இந்த ஆய்வு உதவுகிறது. GDM என்பது கருவுற்றிருக்கும் பெண்களிடம் இருக்கும் அதிக அளவு இரத்த சர்க்கரை ஆகும்.

GDM (அதிக அளவு இரத்த சர்க்கரை) கருவுற்றிற்கும் காலத்தில் பலவித சிக்கல்களை உண்டாக்கும் உதாரணமாக பெரிய குழந்தை, குறிப்பிட்ட காலத்திற்கு முன் பிரசவம் , கருப்பையில் மிக அதிக அளவு நீர், கருப்பையில் குழந்தை இறப்பது போன்றவையாகும்

இந்த ஆய்வானது மருத்துவமனைக்கு வரும் கருவுற்றிருக்கும் தாய்மார்களைப் பாதிக்கும் GDM பற்றியும் ஆபத்துகள் பற்றியும் செய்யப்படும் ஆய்வு ஆகும். நீங்கள் இந்த ஆய்வில் கலந்து கொள்ள விருப்பம் தெரிவித்தால் GTT (குளுகோஸ் டாலரன்ஸ் டெஸ்ட்) என்ற சோதனைக்கு உட்படுத்தப்படுவீர்கள். உங்களுக்கு 75 கிராம் குளுக்கோஸ் தண்ணீரில் கலந்து குடிப்பதற்கு வழங்கப்படும். அவ்வாறு குடித்தபிறகு மூன்று முறை இரத்தப் பரிசோதனை செய்யப்படும். இந்த சோதனையின் முடிவுகள் ஒரு வாரத்தில் தெரிவிக்கபடும். சாட் மருத்துவமனை மருத்துவர் ஒருவர் முடிவுகள் தெரிவதற்கு முன்னர் உங்கள்

வீட்டிற்கு வந்து உங்களை சந்திப்பார். இந்த ஆய்விற்கு சம்பந்தப்பட்ட தேவைப்படும் விபரங்களான வயது, குழந்தைகள் எண்ணிக்கை, குடும்பத்தில் உள்ளோர்களின் சர்க்கரை நோய் பற்றிய விபரம் , சமூகப் பொருளாதார நிலை, உணவுப் பழக்க வழக்கங்கள், உயரம், எடை தோலின் தடிமன் போன்ற விபரங்கள் எடுத்து கொள்ளப்படும். இந்த ஆய்விற்கான காலம் டிசம்பர் 2014 முதல் மே 2015 முடியவாதும்.

இந்த GTT சோதனைக்கு நீங்கள் எந்த கட்டணமும் செலுத்த வேண்டாம். இந்த சோதனையில் பெரிய அளவில் எந்த ஒரு ஆபத்தும் இல்லை. இரத்தம் எடுக்கப்படும் பொழுது மட்டுமே குறைவான மிகலேசான வலி சிலருக்கு ஏற்படலாம். குளுக்கோஸ் கலந்த தண்ணீரை குடிப்பது சிறிது அசௌகரியமாக இருக்கலாம் இந்த முறையில் நிரூபிக்கப்பட்ட ஆபத்துகள் ஏதுமில்லை. இந்த சோதனை முறையில் எந்த காயமும் ஏற்பட வாய்ப்பு இல்லாததால் பொருளாதார இழப்பீடு வழங்கப்பட மாட்டாது.

இந்த ஆய்வில் நீங்கள் கலந்து கொண்டால் உங்களுக்கு GDM பாதிப்பு உள்ளதா என்று கண்டறியப்படும். GDM இருக்குமானால் இந்த சாட் மருத்துமனையில் சிகிச்சை அளிக்கப்படும்.

இந்த ஆய்வின்மூலம் மனித குலத்திற்கும் அறிவியலுக்கும் எதிர்பார்க்கும் பலன்கள் நிச்சயம் கிடைக்கும். GDM மால் பாதிக்கப்பட்ட நோயாளிகளை எப்படி கையாளுவது என்பது பற்றிய மேலாண்மை, இந்த நோயை கட்டுப்படுத்துவது எப்படி, தவிற்பது எப்படி போன்றவைக்கு வழிகாட்டுதலாக இருக்கும்.

இந்த ஆய்வின் முடிவு மருத்துவ ஆய்விதழில் உங்களுடைய பெயர் அடையாளக் குறியீடுகள் தவிர்த்து வெளியிடப்படும் . இருந்த பொழுதும் இதனில் சம்மந்தப்பட்டவர்களின் தனிப்பட்ட விபரங்கள் அவர்களின் அனுமதி பெறாமல் திறனாய்வு செய்யப்படும். தயவு செய்து மேற்கண்ட தகவல்களைக் கவனமாக படித்து எவ்வித தயக்கமும் இன்றி கேள்விகள், தகவல்கள் கேட்கலாம்.

உங்களுக்கு தகவல்கள் அடங்கிய நகல்கள், கேள்விகள் கேட்பதற்கான சந்தரப்பம் இப்போது வழங்கப்பட்டுள்ளது. மேலும், உங்களின் கேள்விகளுக்கான பதில்களும் வழங்கப்படும். உங்களுடைய முழு சம்மதத்துடனும் சுய விருப்பத்துடனும் இந்த ஆய்வில் கலந்துக்கொள்ள வேண்டும். நீங்கள் இதனில் இருந்து எப்பொழுது வேண்டுமானாலும் விலகிக் கொள்ளலாம்.

அவ்வாறு விலகிக் கொள்வதால் சாட் மருத்துவமனையில் உங்களுடைய சிகிச்சைக்கு எந்த பாதிப்பும் ஏற்படாது

இந்த ஆய்வில் கலந்து கொள்கிறீர்களா?

ஆம் ☐ இல்லை ☐

கலந்து கொள்பவரின் பெயர்:

கலந்து கொள்பவரின் கையொப்பம்/ கைரேகை:

இடம்:

தேதி :

கேட்டு விசாரித்தவர் கையொப்பம்:

தேதி:

ஆய்வு செய்து விசாரித்தவர் பெயர்:

இந்த ஆய்வில் ஏற்படக்கூடிய கேள்விகள் ஏதும் இருப்பின் கீழ்க்கண்டவருடன் தொடர்பு கொள்ளவும். மருத்துவர் : கீதா ஆர் 9865779707 Email : drgeethar@cmcvellore.ac.in அல்லது மருத்துவர் : வெங்கடராகவன் 04162284436 அல்லது கிறித்தவ மருத்துவக்கல்லூரி, சமூக நலத்துறை, வேலூர். தொ.பே. 0416-2284207.'

Annexure 5

கிரிக்கல் மருத்துவ கல்லூரி வேலூர்

சமூக மருத்துவ துறை

ஒப்புதல் படிவம்

தலைப்பு

கர்ப்பகால சக்கரை நோய் மற்றும் காரணிகள் பற்றிய ஆராய்ச்சி

ஆய்வு எண் :

ஆய்வாளர் பெயர் :

பிறந்த தேதி / வயது :

பொருளின் பெயர்

1. நான் ..... தேதியிட்ட படிவத்தை படித்து புரிந்து கொண்டேன். மேலும் அதனில் கேள்விகள் கேட்கும் சந்தர்பங்களும் உள்ளன என்பதையும் அறிந்து கொண்டேன்.
2. என்னுடைய சுய விருப்பத்துடன் நான் கலந்து கொள்கிறேன். இதனில் எந்தவித காரணமும் இல்லாமல் எனது மருத்துவ சிகிச்சை, மற்றும் சட்டஉரிமைகளுக்கு பாதிப்பு ஏற்படாது என்பவைதை புரிந்து கொண்டேன்.
3. எனது இரத்தத்தில் சர்க்கரை அளவை பரிசோதிப்பதற்காக இரத்த மாதிரி எடுக்கப்படுகிறது என்றும், எனது உயரம், எடை போன்ற அளவீடுகள் குறித்து என்வீட்டிற்கு வரும் ஆய்வாளர் அவர்களிடம் முழு ஒத்துழைப்பு தரவேண்டும் என்றும், மேலும, எனது ஆரோக்கியம், உடல்நலம் பற்றிய கேள்விகள் கேட்கப்படும் என்றும் புரிந்து கொண்டேன்.
4. ஆய்வின் முதல்வரோ, அவருடன் வேலை செய்பவர்களோ, மற்றும் நியமிக்கப்பட்ட நெறிமுறைப்படுத்தப்பட்ட குழுவினர்களோ, என்னுடைய அனுமதியின்றி ஆய்வு அறிக்கைகளை ஆய்வு செய்து படிக்கவோ, ஆய்வுகளை தொடரவோ, இந்த ஆய்விலிருந்து நான் விலகிவிட்டால், எனது

அடையாளம் மற்றும் தகவல்களை மற்றவர்களிடம் தெரிவிக்கவோ வெளியிடப்படவோ கூடாது என்பதைப் புரிந்து கொண்டேன்.

5. என்னிடமிருந்து பெறப்பட்ட தகவல்களும் சோதனைகளின் முடிவுகளும் அறிவியல் காரணங்களுக்காக மட்டுமே என்பதால் நான் அந்த தகவல்களைப் பயன்படுத்த தடை செய்ய மாட்டேன் என உறுதிசெய்கிறேன்.
6. நான் மேற்கண்ட ஆய்வில் பங்கு ஏற்க முழு சம்மதத்தை தெரிவித்து கொள்கிறேன்.

பங்கேற்பாளர் கையொப்பம் / கைரேகை

தேதி :

பங்கேற்பாளர் பெயர் :

சாட்சிகள் கையொப்பம் / கைரேகை தேதி

சாட்சிகள் கையொப்பம் / கைரேகை தேதி

ஆய்வாளரின் கையொப்பம் தேதி

உங்களுக்கு இந்த ஆய்வு பற்றிய கேள்விகள் இருப்பின் டாக்டர் R.கீதா 9865779707, Email : drgeethar@cmcvellore.ac.in அல்லது ஆலோசகர் டாக்டர் : வெங்கடராகவமோகன் 04162284436 அல்லது சமூக நலத்துறை, கிறித்தவ மருத்துவ கல்லூரி, வேலூர் தொலைபேசி: 0416-2284207 என்ற எண்களில் தொடர்பு கொள்ளவும்.

Annexure 6

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Paedo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

January 23, 2015

Dr. Geetha. R
PG Registrar
Department of Community Health
Christian Medical College, Vellore 632 002

Sub: **Fluid Research Grant Project:**
Prevalence and risk factors of Gestational Diabetes Mellitus among antenatal women attending a secondary care hospital in Vellore.
Dr. Geetha. R, PG Registrar, Dr. Venkat Raghava Mohan. M, Dr. Anne George Cherian, Community Health, CMC, Vellore.

Ref: IRB Min No: 9191 [OBSERVE] dated 08.12.2014

Dear Dr. Geetha. R,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD, MNAMS, DNB (Paedo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Venkat Raghava Mohan, Community Health, CMC, Vellore.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
Tel : 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

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January 23, 2015

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PG Registrar
Department of Community Health
Christian Medical College, Vellore 632 002

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Prevalence and risk factors of Gestational Diabetes.
Mellitus among antenatal women attending a secondary care hospital in Vellore.
Dr. Geetha. R, PG Registrar, Dr. Venkat Raghava Mohan. M, Dr. Anne George Cherian, Community Health, CMC, Vellore.

Ref: IRB Min No: 9191 [OBSERVE] dated 08.12.2014

Dear Dr. Geetha. R,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Mellitus among antenatal women attending a secondary care hospital in Vellore." on December 08th 2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Geetha. R, Venkat Raghava Mohan. M, Anne George Cherian
3. Informed Consent form (English & Tamil)
4. Information Sheet (English & Tamil)
5. Questionnaire
6. No of documents 1-5

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 08th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Name	Qualification	Designation	Other Affiliations
Dr. Ranjith K. Moorthy	MBBS M Ch	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. Niranjan Thomas	DCH, MD, DNB (Paediatrics)	Professor, Neonatology, CMC	Internal, Clinician
Dr. Jacob John	MBBS, MD	Associate Professor, Community health	Internal, Clinician
Dr. Rajesh Kannangai	MD, Ph D.	Professor & In-charge Retrovirus Laboratory (NRL under NACO), Department of Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Anup Ramachandran	Ph. D	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Simon Pavamani	MBBS, MD,	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Dept of Biostatistics, CMC, Vellore	Internal, Statistician
Dr. T. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay Person

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. Denise H. Fleming	B. Sc (Hons), PhD	Honorary Professor, Clinical Pharmacology, CMC, Vellore	Internal, Scientist & Pharmacologist
Dr. Anuradha Rose	MBBS, MD	Assistant Professor, Community Health, CMC, Vellore	Internal, Clinician
Mrs. Sheela Durai	MSc Nursing	Addl. Deputy Nursing Superintendent, Professor of Nursing in Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mr. C. Sampath	BSc, BL	Legal Expert, Vellore	External, Legal Expert
Rev. Joseph Devaraj	B. S., BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Nihal Thomas,	MD, MNAMS, DNB(Endo), FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent.** On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html

IRB Min No: 9191 [OBSERVE] dated 08.12.2014

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Ehaid Grant Allocation:

A sum of 57,700/- INR (Rupee Fifty Seven Thousand Seven Hundred only) will be granted for 6 months.

Yours sincerely

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Venkat Raghava Mohan, Community Health, CMC, Vellore.

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